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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
SEC(2007)

COMMISSION STAFF WORKING DOCUMENT

Written comments of the Community on the OIE Aquatic Animal Health Code Commission meeting October 2006 prior to the next Code Commission meeting March 2007 for consideration in the 75th General Session to be held in May 2007

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EXPLANATORY MEMORANDUM

The Aquatic Animal Health Standards Commission met at the OIE Headquarters in Paris from 2 to 6 October 2006.

These proposals for modifications are for eventual adoption or consideration at the next General Session in May 2007.

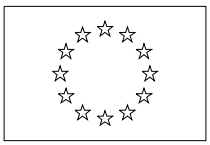
The Community comments need to reach the OIE Headquarters by 10 February 2007 in order to be considered at the next meeting of the Commission in March 2007.

Member Countries should note that, unless stated otherwise, all texts submitted for comment in this report (Part A) may be proposed for adoption at the 75th General Session. Depending on the nature of the comments received on each text, The Aquatic Animal Health Code Commission will indicate in its March 2007 meeting report whether a particular text will be proposed for adoption or held over for further work.

The Commission therefore proposes to the Council to authorise the Commission to present to the OIE, as since 1995, the following written comments in the Annex before 10 February prior to the meeting referred to above. This is in order to allow the OIE to take the Community comments into account during their meeting in March, prior to submission of the final version at the General Session in May 2007. The cover letter to be sent with our response is attached at Annex A (Doc D/(2007) 410110/PR/vb).

In order to facilitate the examination of the comments of the Community, they have been incorporated in boxes into the OIE reports. In this context, the Community thanks the OIE for providing the electronic version of the Report.

ANNEX A



UNION EUROPÉENNE

Bruxelles, le
D(2007) 410110/PR/vb

Object: Meeting of the Aquatic Animal Health Code Commission – March 2007

Dear Bernard,

Please find attached as an annex to this letter the Community comments on the report of the meeting of Code Commission with reference to certain Chapters in the OIE Aquatic Animal Health Code. In order to facilitate the examination of the comments of the Community, they have been incorporated in boxes into the OIE reports. In this context, the Community thanks the OIE for providing the electronic version of the Report.

Thank you for the continued excellent collaboration and trust you will find our comments constructive and useful.

Deputy *Director General*
Paola TESTORI COGGI

Enclosures: 1

Copy: All CVOs Member States, Iceland, Norway, Turkey, Croatia and Switzerland

Dr. B. Vallat
Directeur général OIE
12 Rue de Prony
F-75017 PARIS

Original: English
October 2006

REPORT OF THE MEETING OF THE

OIE AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 2-6 October 2006

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The OIE Aquatic Animal Health Standards Commission (hereafter referred to as the Aquatic Animals Commission) met at the OIE Headquarters from 2 to 6 October 2006. The meeting was chaired by Dr Eva-Maria Bernoth, President of the Commission, and Dr Ricardo Enriquez, Secretary General, acted as Rapporteur. Participants are listed at Appendix I. The adopted Agenda is given at Appendix II.

The Aquatic Animals Commission recognised the contribution of the following Member Countries in providing comments: Australia, Canada, Cuba, the European Community (EC), Japan, New Zealand, Norway, Switzerland, Thailand and the United States of America

(USA). The Commission stressed the importance for feedback for the development of sound international standards that take into account Member Countries' needs.

The Aquatic Animals Commission examined various *Aquatic Animal Health Code* (hereafter referred to as the *Aquatic Code*) texts from its March 2006 report in the light of Member Countries' comments. The outcome of the Aquatic Animals Commission's work is presented as appendices to this report. Additions are shown as double underlined text, with deleted text in strikeout.

Member Countries are invited to submit their comments to the OIE on Appendices III to XXVII of this report prior to 11th February 2007. The comments should be sent preferably by electronic mail to the following address: trade.dept@oie.int.

The table below summarises the texts presented for Member Countries' comment and those for Member Countries' information.

Community Comment.

The Community appreciates the efforts done by the OIE AAC with respect to submitting the report in a reasonable time after the AAC meeting.

However the Community expects the OIE to submit the outcome of the March 2007 meeting as soon as possible after the meeting, in order to allow OIE Member Countries to establish their position before the General Session in May 2007.

Appendix for Member Countries' comment	Appendix number
Definitions (Ch. 1.1.1.)	Appendix III
Diseases listed by the OIE (Ch. 1.2.3.)	Appendix IV
Zoning and compartmentalisation (Ch. 1.4.4.)	Appendix V
Infection with *Bonamia ostreae* (Ch. 2.2.1.)	Appendix VI
Infection with *Bonamia exitiosa* (Ch. 2.2.2.)	Appendix VII
Infection with *Haplosporidium nelsoni* (Ch. 2.2.3.)	Appendix VIII
Infection with *Marteilia refringens* (Ch. 2.2.4.)	Appendix IX
Infection with *Mikrocytos mackini* (Ch. 2.2.5.)	Appendix X
Infection with *Xenohaliotis californiensis* (Ch. 2.2.8.)	Appendix XI
Recommendations for transport (Ch. 1.5.1.)	Appendix XII
Gyrodactylosis (Ch. 2.1.14.)	Appendix XIII
Koi herpesvirus disease (Ch. 2.1.17.)	Appendix XIV
Taura syndrome (Ch. 4.1.1.)	Appendix XV
White spot disease (Ch. 4.1.2.)	Appendix XVI
Yellowhead disease (Ch. 4.1.3.)	Appendix XVII
Tetrahedral baculovirosis (Ch. 4.1.4.)	Appendix XVIII
Spherical baculovirosis (Ch. 4.1.5.)	Appendix XIX
Infectious hypodermal and haematopoietic necrosis (Ch. 4.1.6.)	Appendix XX
Crayfish plague (Ch. 4.1.7.)	Appendix XXI
Infectious myonecrosis (Ch. 4.1.9.)	Appendix XXII

Necrotising hepatopancreatitis (Ch. 4.1.10.)	Appendix XXIII
White tail disease (Ch. 4.1.11.)	Appendix XXIV
Hepatopancreatic parvovirus disease (Ch. 4.1.12.)	Appendix XXV
Mourilyan virus disease (Ch. 4.1.13.)	Appendix XXVI
Koi herpesvirus disease (*Aquatic Manual* Chapter)	Appendix XXVII
Appendix for Member Countries' information	**Appendix number**
Abalone viral mortality – disease information card	Appendix XXVIII
Mourilyan virus – disease information card	Appendix XXIX
Infectious myonecrosis – disease information card	Appendix XXX
White tail disease – disease information card	Appendix XXXI
Report of the *ad hoc* Group on the OIE List of Aquatic Animal Diseases	Appendix XXXII
Report of the *ad hoc* Group on Chapters for Mollusc Diseases	Appendix XXXIII
Report of the *ad hoc* Group on Chapters for Crustacean Diseases	Appendix XXXIV
Report of the *ad hoc* Group on Amphibian Diseases	Appendix XXXV
Questionnaire on amphibian trade and diseases	Appendix XXXVI
Position paper on pathogen strain differentiation	Appendix XXXVII
Work plan	Appendix XXXVIII

1. Activities and progress of *ad hoc* Groups

The Aquatic Animals Commission reviewed the progress made by those *ad hoc* Groups that have met since the previous meeting of the Commission:

I. OIE *ad hoc* Group on Aquatic Animal Health Surveillance, 24-26 July 2006

II. OIE *ad hoc* Group on Chapters for Mollusc Diseases for the OIE *Aquatic Animal Health Code*, 8-10 August 2006

III. OIE *ad hoc* Group on the OIE List of Aquatic Animal Diseases - Mollusc Team - for the OIE *Aquatic Animal Health Code*, 8-10 August 2006

IV. OIE *ad hoc* Group on Amphibian Diseases, 11-13 September 2006

V. The OIE *ad hoc* Group on the OIE List of Aquatic Animal Diseases – Crustacean Team - and the OIE ad *hoc* Group on Chapters for Crustacean Diseases for the OIE *Aquatic Animal Health Code* met in conjunction with this meeting of the Commission.

The Commission noted the overall progress made by the *ad hoc* Groups against their terms of reference and expressed its appreciation for the excellent work of the experts involved. The Commission recognised the efficiency of face-to-face meetings and agreed that this way of working should be continued.

Specific items related to the above *ad hoc* Groups will be dealt with in specific agenda items below.

2. ***Aquatic Animal Health Code***

The Community appreciates the efforts done by the OIE AAC with respect to amendments of the Code. In general, the Community can support the proposal for updates. Technical comments are included in the relevant Appendices.

2.1. General comments on the March 2006 report

The EC had questioned the need for certificates for non-viable molluscs or mollusc products as well as for fish products arguing that given the nature and intended use of the commodities, a request for health certificates would not be justifiable. The Aquatic Animals Commission is of the view that a health certificate, even for dead molluscs and their products or eviscerated fish products, is necessary to attest the health status of the exporting country, especially if the country claims to be free from the disease in question. Additionally, if these commodities were considered to be safe by the OIE *ad hoc* Groups, they would be suggested for listing under the relevant article of each disease chapter.

Community comment

The Community insists on its previous comment regarding the need for certificates for non viable mollusc as well as for fish and crustacean products. To request animal health certificates for these commodities, taking into account their intended use and the nature of the commodities (which by nature cannot be for further farming), seems non-justifiable.

The Community would propose to merge, in all the disease chapters, the articles "Importation of aquatic animal products from an area not declared free" and "Importation of aquatic animals products from an area declared free" into one single article "Importation of aquatic animals products". This new single article will address in a better way the risks posed by the traded of aquatic animal products.

Furthermore, the EC asked that disinfected eggs be included in the list of safe commodities for certain diseases. The Aquatic Animals Commission had considered listing disinfected eggs as a safe commodity, but thought that scientific evidence showing that they pose no risk was necessary before their inclusion could be proposed. The Commission is looking forward to receiving the reports from the "EU funded study Fish Egg Trade", as referred to by the EC in its comments, and will forward it to the OIE *ad hoc* Group on Chapters for Fish Diseases for the OIE *Aquatic Animal Health Code*.

Community comment

The Community puts forward as an attachment to the report the "EU funded study Fish Egg Trade"for its consideration. It gives a sound scientific basis to consider disinfected eggs of certain fish species under certain circumstances as not likely to spread some diseases. The concluclusions of the study suggest that Viral haemorrhagic septicaemia, Infectious salmon anaemia and Infectious haemotopoietic necrosis may be effectively prevented by common egg disinfection procedures.

We invite the OIE AAC to assess the "EU funded study Fish Egg Trade"with the aim to draft a new chapter in the Aquatic Code addressing the certification requirements and conditions to be met to facilitate safe trade as regards certain diseases. Comparing to trade with live fish, disinfected eggs - following the application of appropriate disinfection procedures - may be regarded as a commodity posing a lower risk concerning transmission of certain diseases; accordingly such trade should be encouraged. Specific trade requirements for disinfected eggs, corresponding to the lower risks and similar to what is in place for semen and embryos in the Terrestrial Code may be appropriate. To address the same objective, the Community would also like the OIE AAC to reinstate and update and the egg disinfection chapter in the Aquatic Code or Manual.

2.2. Definitions (Chapter 1.1.1.)

The Aquatic Animals Commission addressed the comment raised by Canada during the past General Session and agreed on the need to introduce a definition for veterinary para-professionals; the definition proposed is based on the one given in the OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*).

The Commission updated the Chapter on zoning (see below). This update required new definitions for *aquatic animal health status*, *biosecurity plan*, *compartmentalisation*, *subpopulation* and an update of the definition for *zoning*.

The Commission modified the definition of *infection* to distinguish it from infestation by parasites. Accordingly the definition of *disease* was updated and a definition for *infestation* was drafted.

The Commission submits the amended and new definitions for Member Countries' comment at Appendix III with the view for proposing their adoption at the May 2007 General Session.

2.3. Revision of the list of diseases (Chapter 1.2.3.)

Community Comment

The Community raises a concern regarding the continuously increasing number of listed crustacean diseases and the relatively low number of notifications made by the OIE Member Countries.

The Aquatic Animals Commission addressed the proposal from Thailand to delist tetrahedral baculovirosis and spherical baculovirosis. The Commission reviewed the suggestions of the *ad hoc* Group on the OIE List of Aquatic Animal Diseases for the OIE *Aquatic Animal Health Code* – Crustacean Team on the comments received from Thailand and recommended these two diseases be retained on the OIE list of diseases at this time.

The Commission noted that there had been no Member Country comments regarding the suggested addition of white tail disease, hepatopancreatic parvovirus disease and Mourilyan virus disease as proposed in the March 2006 report. The Commission therefore confirms its proposal to add these emerging diseases to the list. It also recommends the removal of the classification as [under study] for necrotising hepatopancreatitis and infectious myonecrosis. The Commission also presents, for Member Countries' information, the disease information cards for white tail disease, hepatopancreatic parvovirus disease and Mourilyan virus disease, prepared by the *ad hoc* Group at Appendices XXIX to XXXI.

The updated version of Chapter 1.2.3. is given at Appendix IV for Member Countries' comment with the view to proposing it for adoption at the May 2007 General Session.

The Commission noted the report of the *ad hoc* Group on the OIE List of Aquatic Animal Diseases - Mollusc Team. The abalone viral mortality disease information card drafted by the *ad hoc* Group was reviewed and modified as shown at Appendix XXVIII.

The Commission recommends the use of disease cards for Member Countries' reporting purposes until a chapter on the relevant disease is adopted and included in the OIE *Manual of Diagnostic Tests for Aquatic Animals* (hereafter referred to as the *Aquatic Manual*).

The Commission reviewed the preliminary assessment made by the *ad hoc* Group on the Sabellid Worm (*Terebrasabella heterouncinata*) and noted that a full assessment would be developed at the next meeting of the *ad hoc* Group.

Addressing the comment from Norway recommending reconsidering the delisting of bacterial kidney disease (BKD), the Commission pointed out that the deletion of BKD from Chapter 1.2.3. of the *Aquatic Code* was adopted at the 2006 General Session and that a chapter on BKD is, however, retained in Part 2 of the *Aquatic Code*.

The report of the *ad hoc* Group on the OIE List of Aquatic Animal Diseases is attached at Appendix XXXII.

2.4. Zoning and compartmentalisation (Chapter 1.4.4.)

The Aquatic Animals Commission considered the ongoing work by the OIE Terrestrial Animal Health Standards Commission (hereafter referred to as the the Terrestrial Code Commission) on zoning and compartmentalisation.

On the basis of the most recent update of the *Terrestrial Code* chapter on zoning and compartmentalisation, the Aquatic Animals Commission produced a new draft for the *Aquatic Code*, which is given at Appendix V for Member Countries' comment with the view to proposing it for adoption at the May 2007 General Session. This is presented as a clean text because the chapter was completely revised.

2.5. Disease chapters

The OIE *ad hoc* Group on Chapters for Mollusc Diseases for the OIE *Aquatic Animal Health Code*, in its August 2006 meeting, addressed Member Countries' comments on the Commission's March 2006 meeting report. The *ad hoc* Group also took into account comments provided by the OIE Reference Laboratory for Infection with *Mikrocytos mackini*. As a result, the *ad hoc* Group revised some chapters as shown in its report appended at Appendix XXXIII.

The Commission noted the report of the *ad hoc* Group and proposes updated versions of the mollusc disease chapters.The updated versions are given at Appendices VI to XI for Member Countries' comment, with the view to proposing them for adoption at the May 2007 General Session.

One Member Country had queried the inclusion in point 1c) of Article 3 of a particular species that is not part of the scope in Article 1, in several mollusc disease chapters. The Commission considered that it is useful to list those species as they are known to be non-susceptible to the disease in question. This makes the conduct of a full risk analysis, as indicated in point 3 of the same Article,

unnecessary when the scientific evidence is present (refer to the *ad hoc* Group's report at Appendix XXXIII).

The Commission addressed the recommendations of the *ad hoc* Group on the issue of risks associated with accompanying transport water for eggs and gametes. It supported the *ad hoc* Group's views and recommended that Chapter 1.5.1. of the *Aquatic Code* be updated to better address the treatment of the transport water, especially for gametes, eggs and larvae. Chapter 1.5.1. is submitted for Member Countries' comment at Appendix XII with the view to proposing its adoption at the May 2007 General Session.

The Commission addressed the draft revised chapter on gyrodactylosis, prepared by Prof. Barry Hill, the chair of the OIE *ad hoc* Group on Chapters for Fish Diseases for the OIE *Aquatic Animal Health Code*. The revision takes into account Member Countries' comments received on the August 2005 report. The Aquatic Animals Commission accepted this revision and submits the Chapter for Member Countries' comment at Appendix XIII with the view to proposing its adoption at the May 2007 General Session.

Community Comment

The Community has strong reservations on the proposed chapter on Gyrodactylus, and would ask the OIE to take our comments into account.

The Commission addressed the new draft chapter on koi herpesvirus disease (KHVD), submitted by Prof. Barry Hill. This work was initiated following the inclusion of KHVD in Chapter 1.2.3. at the May 2006 General Session. The Commission accepted this draft chapter and submits it for Member Countries' comment at Appendix XIV with the view to proposing its adoption at the May 2007 General Session.

The Commission addressed the comments received from the EC and Canada on the reference to the ICES Guidelines (in Article 8 of the proposed crustacean disease chapters). The Commission noted that methods for disease prevention and control are within the mandate of the OIE; hence it considers it appropriate to reference such an international code as the ICES Code of Practice on the Introductions and Transfers of Marine Organisms. The Commission noted the request from Canada to include a reference to the ICES Code in the fish and mollusc disease, and will refer this to its *ad hoc* Groups for consideration.

Community comment.

The Community raises a concern about the use of reference in the Aquatic Code to documents outside the Aquatic Code (in this case the ICES guidelines), because of the

lack of clarity of the validity of such external documents and any changes made to them.

In addition, the Community queries the inclusion of points 2 and 3 in Articles 4.1.X.8 in all crustacean disease chapters. In accordance with the "Foreword" and "Guide to the use of the Aquatic Animal Health Code " part 2, 3 and 4 of the Code are designed to prevent the disease in question being introduced into the importing country. Thus, the Community would argue that guidance for establishing new genetic lines (as referred to in point 2 of articles 4.1.X.8), is beyond the scope of the disease chapters of the Code. The Community notes that such guidance in not included in any of the fish and mollusc disease chapter respectively. If the OIE retains the need for such guidance, they should be changed into guidelines for establishing (specific) pathogen free populations, and included in Part 5 of the Code or published elsewhere (f.x. in a separate OIE publication series on animal disease control and eradication). The Community would be pleased to provide the OIE wih assistance in drafting such guidance.

The Comunity would like to highlight the work ongoing in the EU concerning the use of alien and locally absent species. The Community will be pleased to send that document as soon as it will be finished.

The Aquatic Animals Commission reviewed the updated and new chapters on crustacean diseases prepared by the OIE *ad hoc* Group on Chapters for Crustacean Diseases for the OIE *Aquatic Animal Health Code* (the report is attached at Appendix XXXIV). The Aquatic Animals Commission accepted these updated and new chapters and submits them for Member Countries' comment at Appendices XV to XXVI, with the view to proposing their adoption at the May 2007 General Session.

The Commission agreed with the recommendation of the *ad hoc* Group on the possibility to use means other than boiling for cooking to produce products that may be traded without any disease-specific conditions (Article 3); Australia (who submitted the comment) is invited to provide further details on additional methods for cooking (other than boiling).

To better identify those diseases for which specific disease chapters are retained in the *Aquatic Code* despite their removal from the list of diseases in Chapter 1.2.3. (i.e. channel catfish virus disease,viral encephalopathy and retinopathy, infectious pancreatic necrosis, infectious salmon anaemia, bacterial kidney disease [*Renibacterium salmoninarum*], enteric septicaemia in catfish [*Edwardsiella ictaluri*], piscirickettsiosis [*Piscirickettsia salmonis*] and white sturgeon iridoviral disease), the Aquatic Animals Commission proposes to include the following explanatory note "Nota bene: This disease does not meet the listing criteria in Chapter 1.2.2. Therefore, Member Country obligations related to its notification to the OIE do not apply. Member Countries are free to decide for a voluntary notification.

Community Comment.

The Community supports the approach concerning the exchange of epidemiological information of non-listed diseases between trading partners. The Community would argue that a notification requirement of non-listed diseases with epidemiological significance to other countries is foreseen by Article 1.2.1.3. point 1e).

However, the Community would like to have a clear explanation of how the proposed voluntary notification of non-listed diseases system would be managed. According to our knowledge on WAHIS, the system only makes it possible for the Member Countries to make voluntary notification if the non-listed diseases are included in the list of diseases in the system. If non-listed diseases are included in WAHIS, it could be difficult to know whether the data regarding such disease are compulsory notifiable or are notifiable on a voluntary basis. The Community would encourage the OIE to see how the WAHIS could be adapted to a system of compulsory and voluntary notifications.

2.6. New draft appendices on aquatic animal welfare

Community comment

The Community supports the initiative and looks forward to the outcome of the OIE Animal Welfare Working Group.

The Aquatic Animals Commission welcomed the considerable interest shown by Member Countries on this topic evidenced by the many constructive comments received. Besides the numerous technical comments, there were also concerns of a more fundamental nature that will need further consideration:

a) Although the draft aquatic animal welfare guidelines took into consideration the already adopted guidelines on terrestrial animal welfare, and this approach was welcomed, further work should be conducted to provide scientific evidence in support of the draft aquatic animal welfare guidelines.

b) The applicability to aquatic animals of the "five freedoms" should be reconsidered assessing scientific evidence for or against this issue.

c) Comments from Member Countries with regard to the relationship between the guidelines on animal health and those on animal welfare are referred to the Animal Welfare Working Group for detailed consideration.

d) The proposed need for certification of an "aquatic animal technician" was strongly criticised by several Member Countries.

e) Several Member Countries expressed the view that the draft aquatic animal welfare guidelines should be less prescriptive and more outcome based.

f) Implications the current draft aquatic animal welfare guidelines have for the wild capture fishing industry must be clarified.

g) The fish species considered by the draft aquatic animal welfare guidelines should include all the commonly farmed species.

The Aquatic Animals Commission agrees with these comments and requests the OIE Animal Welfare Working Group to address these issues and the numerous technical comments and provide scientific justification for the recommendations reached.

2.7. Antimicrobial resistance in the field of aquatic animals

Dr Elisabeth Erlacher-Vindel, Deputy Head of the Scientific and Technical Department, joined the meeting. She informed the Aquatic Animals Commission of the outcomes of the FAO/WHO/OIE expert consultation on Antimicrobial Usage in Aquaculture and Resistance, which took place in Seoul (Republic of Korea) from 13 to 17 June 2006. The official report would be available shortly.

The Commission acknowledged the need for further discussion on this topic and agreed to identify relevant experts in the field of antimicrobial resistance in aquatic

animal health to support the work of the Biological Standards Commission which has primary responsibility for the matter.

2.8. Aquatic animal feeds

The Aquatic Animals Commission noted that the OIE *ad hoc* Group on aquatic animal feeds, chaired by Prof. Eli Katunguka-Rwakishaya, is scheduled to meet in December 2006.

2.9. Diseases of amphibians

The Aquatic Animals Commission acknowledged the meeting report of the *ad hoc* Group on amphibian diseases and has included it as Appendix XXXV for Member Countries' information. The Commission noted that the *ad hoc* Group would need to meet again in early 2007 to assess the outcomes of the questionnaire on amphibian trade and diseases and submit a final report to the Commission with recommendations.

The Commission finalised the questionnaire and appended it to this report (Appendix XXXVI) for Member Countries' information. The Commission recommended this questionnaire be sent out as soon as possible by the OIE Central Bureau to all OIE Delegates with a copy of the *ad hoc* Group's report attached.

3. **Joint meeting with the Terrestrial Animal Health Standards Commission**

The Terrestrial Code Commission explained that, due to the physical size of the *Terrestrial Code*, it was planned to publish the next edition as two volumes.

Future editions of both Codes could be merged into one Code that would eventually be printed in several volumes. The Aquatic Animals Commission agreed that there may be benefit in producing a volume that includes general provisions pertinent to both aquatic and terrestrial standards.

Both Commissions acknowledged the harmonisation work that already had been accomplished and agreed that these efforts should be pursued, appreciating that consistent rather than identical texts would need to be prepared.

Community comment

The Community fully supports the view of both Commissions. Disease chapters should be adapted to the specific characteristics of each disease.

With the intent to assist Member Countries in the evaluation of their national Veterinary Services, the OIE is developing the Performance, Vision and Strategy (PVS) instrument. The Commissions discussed the future development of this instrument and next steps in the development of a Handbook and Indicators for conducting evaluations. The PVS Instrument, the Handbook and the Indicators will not form part of any of the Codes. Rather, they will be published by the OIE as an official tool for use in the evaluation of Veterinary Services.

Both Commissions agreed on the way forward for an harmonised approach to the concepts of zoning and compartmentalisation (see point 2.4 of this report).

4. **Joint meeting with the Animal Health Information Department**

Dr Karim Ben Jebara, Head of Information Department, joined the meeting for this agenda item.

4.1. Update on the new aquatic and terrestrial notification systems and WAHIS

Dr Ben Jebara informed the Commission that all four components (immediate notification, follow-up reports, six-monthly reports and annual reports) of the World Animal Health Information System (WAHIS) are now active. The Delegates had been provided with password protected access and were requested to nominate through the application national focal points for disease notification to the OIE (aquatic and/or terrestrial). The new system that promotes an environment of transparency for compiling data, World Animal Health Information Database (WAHID), would be launched shortly.

4.2. Emerging aquatic animal diseases

The Aquatic Animals Commission had become aware of some confusion caused by the difference between the list of diseases as displayed in Chapter 1.2.3. and the diseases listed in Part 2 of the *Aquatic Code*: Chapter 1.2.3. does not distinguish those diseases meeting the full listing criteria (Article 1.2.2.1.) from those meeting the emerging diseases listing criteria (Article 1.2.2.2.). For those emerging diseases, an *Aquatic Code* chapter has not yet been prepared, therefore these diseases do not appear in Part 2 of the *Aquatic Code*.

The Commission therefore proposes to identify those emerging disease by a footnote in Chapter 1.2.3. as shown in Appendix IV and by inserting a corresponding blank chapter labelled as [under study] in part 2 of the *Aquatic Code*.

4.3. Definition of "Case" for the purposes of WAHIS

One Member Country commented that because the new OIE system of immediate notification (WAHIS) calls for an indication of the number of cases, a suitable definition for case should be provided in the *Aquatic Code*. The Aquatic Animals Commission was advised by Dr Ben Jebara that the term "case" was explained in the OIE guidelines for completing the new form as well as defined in Chapter 1.1.1 (Definitions) of the *Terrestrial Code*.

However, the Commission was of the view that the current explanation of "case" in those guidelines may pose difficulties for reporting on aquatic animal disease events. This is because "case" is explained as "moribund animals and animals that died from the disease" in the guidelines, and defined as "an individual animal infected by a pathogenic agent, with or without clinical signs" in the *Terrestrial Code*, but disease events in aquatic animals typically affect very large numbers of individuals. The Commission encourages Member Countries to convey their experience in using those forms to the OIE Information Department.

5. **Joint meeting with the Publications Department**

Dr Paul-Pierre Pastoret and Ms Annie Souyri, respectively Head and Deputy Head of the Publications Department, joined the meeting for this agenda item.

They reported progress on the preparation of the OIE *Scientific and Technical Review*: Issue on aquatic animal health, which is due to be published in April 2008. All but two of the invited authors agreed to contribute to this publication. The Aquatic Animals Commission suggested possible replacements for the two remaining contributions.

6. **The role and activities of the OIE in the field of aquatic animal health**

6.1. International meetings

6.1.1. Regional Commission Conferences

Prof. Hill reported on his presentation to the Regional Commission for Europe in September 2006. The OIE Delegates had reacted positively to the information provided on the continuing global growth of aquaculture and the need for greater involvement of Veterinary Services in aquatic animal health.

The presentation provided further information on amphibian trade and diseases. Prof. Hill stressed how much the OIE Director General had supported this issue in commenting to the Delegates after the presentation.

The Aquatic Animals Commission emphasised the usefulness of such regular updates on aquatic animal health to national Delegates through the Regional Commission Conferences and recommends continuation of this practice.

The Commission noted the schedule for the upcoming Regional Commission Conferences and agreed the following representation for follow-up presentations on developments in aquatic animal health:

- Regional Commission for the Americas (November 2006): Dr Ricardo Enriquez, Secretary General of the Aquatic Animals Commission;

- Regional Commission for Africa (February 2007): Prof. Eli Katunguka-Rwakishaya, Member of the Aquatic Animals Commission.

6.1.2. International Forum on Infectious Myonecrosis in farmed shrimp, 8-9 August 2006, Managua, Nicaragua

Prof. Lightner reported on the International Forum on Infectious Myonecrosis Virus (IMN) in Shrimp Farming held in the City of Managua. This Forum was organised by the Ministry of Agriculture and Forestry and the OIE Regional Representation for the Americas through its expert group on crustaceans, and sponsored by the Nicaraguan Association of Aquaculture Farmers (ANDA). It was attended by representatives from public institutions, universities, ANDA members and non-member producers, cooperatives and members of the Inter-American Committee on Aquatic Animal Health. Prof. Lightner presented technical papers on the global status of IMN and on the occurrence of a new shrimp disease in Central America with signs that mimic those presented by shrimp with IMNV. He also reported on the current known distribution of strains of Taura syndrome virus in the Americas with a particular emphasis on central America. The report prepared by the organisers has been published and is available at the web site of the OIE Regional Representation for the Americas (www.rr-americas.oie.int).

6.1.3. Fifth Annual General Meeting of Network of Aquaculture Centres in Asia-Pacific (NACA) Asia Regional Advisory Group on Aquatic Animal Health, 22-24 November 2006, Bangkok, Thailand

Dr Bernoth, President of the Aquatic Animals Commission, will represent the Commission at the fifth General Meeting of NACA's Asia Regional Advisory Group on Aquatic Animal Health and will report on progress with further development of the *Aquatic Code* and *Manual* and other new initiatives of the Commission. She will also report on the outcomes of the OIE Global Conference on Aquatic Animal Health.

6.1.4. First International Conference of OIE Reference Laboratories and Collaborating Centres, 3-5 December 2006, Florianopolis, Brazil

The Commission noted the programme of the Conference on the OIE website and the provision of limited time for the special workshop on viral strain differentiation and listing and notification of diseases by strain/genotype. The Commission feels that this would give insufficient time to address the subject adequately and requested that additional time be provided by the organisers. As a result, the special workshop will be held from 10 a.m. to 4 p.m. on Sunday 2 December, before the opening ceremony. The conclusions and recommendations will be prepared on Monday 3 December in parallel with Session 2. The draft recommendations will be presented to the Conference at the end of Session 2 from 12 to 12.15 p.m. The final recommendations will be presented at the end of the Conference.

6.2. Cooperation with FAO

Dr Bernard Vallat, the OIE Director General, joined the Aquatic Animals Commission for this agenda item.

Dr Rohana P. Subasinghe, Senior Fishery Resources Officer of FAO, provided a brief overview of past and present FAO/OIE collaboration on aquatic animal health activities. He mentioned the significant achievements of this cooperation in capacity building to improve aquatic animal health status, notably in Asia and the Pacific, with particular involvement of NACA. He also mentioned that, so far, this collaboration is yet to be initiated in Latin America and Africa. Given the predicted reliance on aquaculture for global aquatic food production in the future, Dr Subasinghe suggested that enhanced cooperation between FAO and OIE in aquatic animal health could provide significant contribution to the global efforts on sustainable aquatic production and invited Dr Vallat to meet the FAO Assistant Director General in charge of aquatic animals.

Dr Vallat noted the points raised and agreed that cooperation between FAO and OIE could be strengthened on aquatic animal health. He mentioned that the recently renewed agreement between FAO and OIE clearly identifies the respective and collaborative roles and responsibilities of the two organisations, in particular, OIE's responsibility in setting aquatic animal health standards and the FAO's responsibility in assisting developing Member Countries in the implementation. Dr Vallat mentioned that the Global Framework on the Control of Transboundary Diseases (GF-TADs) has been jointly set up by OIE and FAO; however, aquatic animal health is, as yet, not included. He clarified that regional policies are currently discussed in five OIE/FAO regional steering committees whose secretariat is managed by the OIE Regional Representatives.

The Commission agreed that a priority area for cooperation between the two organisations on aquatic animal health would be the governance for aquatic animal health in Member Countries. In this regard, the Commission expressed the importance of the recommendations arising from the OIE Global Conference on Aquatic Animal Health. The Commission agreed that a formal meeting between

FAO and OIE should be held in the near future to discuss ways to improve collaboration.

7. ***Manual of Diagnostic Tests for Aquatic Animals***

7.1. Feedback on the fifth edition of the *Aquatic Manual*

Community comment

If intermittent amendments are done in the web version of the Aquatic Manual, for the sake of transparency, we encourage the OIE to identify in a clear manner the amendments done on the web version compared to the published version.

Feedback to Members of the Commission from individual experts on the fifth edition of the *Aquatic Manual* had been positive. The *Aquatic Manual* is widely regarded to be the definitive guide to diagnostic methods for listed aquatic animal diseases and other diseases of importance to international trade. It was also appreciated that chapters for delisted diseases had been retained. The next edition is planned for publication in 2009; intermittent changes, if adopted by the International Committee, will be added to the web version of the *Aquatic Manual*.

The Commission felt that for delisted diseases for which chapters are retained in the *Aquatic Manual*, the corresponding Reference Laboratories should be requested to update the chapters.

7.2. Terms of Reference for a proposed Consultant Editor for the next edition of the *Aquatic Manual*

In follow-up to its last report in which the Commission had considered convening an *ad hoc* Group (of fish, mollusc and crustacean disease experts) with an editorial focus to resolve the increasing volume and complexity of issues relating to the *Aquatic Manual*, the Commission now felt that appointing a Consultant Editor may be a more suitable approach. The Biological Standards Commission have adopted a similar approach for the *Terrestrial Manual*. The Commission reviewed and modified the proposed Terms of Reference for such a Consultant Editor, and discussed possible candidates, who would be contacted by the OIE Central Bureau.

7.3. *Ad hoc* Group on Surveillance: Revision of chapters for the *Aquatic Code* and *Manual*

Community comment

The Community supports the initiative and looks forward to the outcome of the *ad hoc* Group on Surveillance. We would ask the OIE to provide us with the draft texts as soon as they are available for comments. Due to the importance of these texts, they should undergo a thorough examination and assessment and should therefore not be put forward for adoption in the General Session in 2007.

Prof. Hill reported on the progress made by the *ad hoc* Group on Surveillance at its meeting in July, and requested out of session comments from the Commission on the initial draft texts. The Group would meet again in January 2007 to finalise the draft texts in time for them to be appended to the report of the meeting of the Commission in March 2007.

7.4. Review of Chapter 1.1.5. on methods for disinfection of aquaculture establishments

The Commission reviewed the *Aquatic Manual* chapter on methods for disinfection of aquaculture establishments and decided that some restructuring is needed to improve clarity and avoid repetition. This would be a task for the Consultant Editor.

7.5. Information on newly listed diseases (KHVD, abalone viral mortality)

An expert from the OIE Collaborating Centre for Information on Aquatic Animal Diseases had prepared a draft chapter on koi herpesvirus disease (KHVD). The chapter was endorsed by the Commission and can be found at Appendix XXVII for Member Countries' comment with a view to proposing it for adoption in May 2007.

For both recently added diseases (namely KHVD and abalone viral mortality), the Commission is preparing disease cards. These cards, when finalised, will be made available on the Commission's web pages.

Disease cards for crustacean diseases proposed for lising are attached to this report (infectious myonecrosis, white tail disease, and Mourilyan virus disease) or are in preparation (necrotising hepatopancreatitis and hepatopancreatic parvovirus disease). Should the OIE International Committee decide to list these diseases, the related disease cards will be made available on the Commission's web pages.

8. **OIE Reference Laboratories**

8.1. Review of the list of Reference Laboratories: New possible candidates for KHVD and abalone mortality

In response to a letter in July 2006 from the OIE Director General to OIE Delegates requesting applications for Reference Laboratory status especially for diseases for which there is currently no designated laboratory, one application had been received for OIE Reference Laboratory status for koi herpesvirus disease.

A second application was received after the meeting and circulated electronically to the members. The Commission was satisfied with the information provided on the laboratories and the designated experts.

The Aquatic Animals Commission welcomed these applications and encourages Member Countries to submit further applications (especially for abalone viral mortality) by 10 February 2007 for review at its next meeting in March 2007.

8.2. Concept paper on viral strain differentiation for the Conference of OIE Reference Laboratories and Collaborating Centres

Community comment

The Community welcomes this concept paper and encourages the OIE to go into this topic. The Community would be pleased to provide the OIE with assistance.

The Commission reviewed a draft concept paper, prepared by Dr Franck Berthe, Member of the Aquatic Animals Commission, and made some minor modifications. This concept paper will provide the basis for discussion at the special workshop to be held during the Conference in Brazil (see above). It is attached for information at Appendix XXXVII.

9. **Any other business**

9.1. Update of the Commission's web pages

The Commission discussed the current design of the web pages and agreed to add a facility that draws more attention to new and emerging diseases.

9.2. Inclusion of aquatic reptilian diseases in the remit of the OIE

The Aquatic Animals Commission discussed a suggestion from the Central Bureau to consider including diseases of aquatic reptiles (turtles, crocodiles, etc.) diseases in the remit of the OIE. The Commission considered that this issue would be better addressed once a decision on including amphibian diseases has been taken.

9.3. Review of the Aquatic Animals Commission's work plan for 2007-2008

The Aquatic Animals Commission reviewed its work plan for 2007-2008. The work plan is appended at Appendix XXXVIII for Member Countries' information.

10. Date of the next meeting

The Aquatic Animals Commission proposed to meet on 5-9 March 2007.

.../Appendices

Appendix I

MEETING OF THE OIE

AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 2-6 October 2006

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Appendix II

MEETING OF THE OIE

AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 2-6 October 2006

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Adopted agenda

1. **Activities and progress of *ad hoc* Groups**
2. ***Aquatic Animal Health Code***
   - *2.1.* General comments on the March 2006 report
   - *2.2.* Definitions (Chapter 1.1.1.)
   - *2.3.* Revision of the list of diseases (Chapter 1.2.3.)
   - *2.4.* Zoning and compartmentalisation (Chapter 1.4.4.)
   - *2.5.* Disease chapters
   - *2.6.* New draft appendices on aquatic animal welfare
   - *2.7.* Antimicrobial resistance in the field of aquatic animals
   - *2.8.* Aquatic animal feeds
   - *2.9.* Diseases of amphibians
3. **Joint meeting with the Terrestrial Animal Health Standards Commission**
4. **Joint meeting with the Animal Health Information Department**
   - *4.1.* Update on the new aquatic and terrestrial notification systems and WAHIS
   - *4.2.* Emerging aquatic animal diseases
   - *4.3.* Definition of “Case” for the purposes of WAHIS
5. **Joint meeting with the Publications Department**
6. **The role and activities of the OIE in the field of aquatic animal health**
   - *6.1.* International meetings
     - 6.1.1. Regional Commission Conferences
     - 6.1.2. International Forum on Infectious Myonecrosis in farmed shrimp, 8-9 August

2006, Managua, Nicaragua

6.1.3. Fifth Annual General Meeting of NACA's Asia Regional Advisory Group on Aquatic Animal Health, 22-24 November 2006, Bangkok, Thailand

6.1.4. First International Conference of OIE Reference Laboratories and Collaborating Centres, 3-5 December 2006, Florianopolis, Brazil

6.2. Cooperation with FAO

7. ***Manual of Diagnostic Tests for Aquatic Animals***

   7.1. Feedback from the Commission on the 5th edition of the *Aquatic Manual*

   7.2. Terms of Reference for a proposed Consultant Editor for the next edition of the *Aquatic Manual*

   7.3. *Ad hoc* Group on Surveillance: Revision of chapters for the *Aquatic Code* and *Manual*

   7.4. Review of Chapter 1.1.5. on methods for disinfection of aquaculture establishments

   7.5. Information on newly listed diseases (KHVD, abalone viral mortality)

8. **OIE Reference Laboratories**

   8.1. Review of the list of Reference Laboratories: New possible candidates for KHVD and abalone mortality

   8.2. Concept paper on viral strain differentiation for the Conference of OIE Reference Laboratories and Collaborating Centres

9. **Any other business**

   9.1. Update of the Commission's web pages

   9.2. Inclusion of aquatic reptilian diseases in the remit of the OIE

   9.3. Review of the Aquatic Animals Commission's work plan for 2007-2008

10. **Date of the next meeting**

Appendix III

CHAPTER 1.1.1.

DEFINITIONS

Article 1.1.1.1.

Community comment

The Community agrees with the proposed amendments but would like to have its comments taken into account.

Aquatic animal health status

means the status of a country, *zone* or *compartment* with respect to an *aquatic animal disease*, according to the criteria listed in the relevant chapter of the *Aquatic Code* dealing with the *disease*.

Biosecurity plan

means a plan that identifies potential pathways for the introduction and spread of *disease* in a *zone* or *compartment*, and describe the measures which are being or will be applied to mitigate the *disease* risks, in accordance with the recommendations in the *Aquatic Code*. The plan also describes how these measures are audited to ensure that the risks are regularly re-assessed and the measures adjusted accordingly.

Compartmentalisation

means identifying *compartments* for disease control or *international trade* purposes.

Disease

means clinical or non clinical *infection* or *infestation* with one or more of the aetiological agents of the diseases referred to in the *Aquatic Code*.

Infection

means the presence of a multiplying or otherwise developing or latent disease agent in ~~or, for ectoparasites, on~~ a host.

The Community suggest, for the sake of clarity, the replacement the word "large" by "significant" so the definition of infestation would read as:
"Infestation"
means the presence in significant numbers of a multiplying parasitic, or comensal agent on a host so as to cause damage or disease.

Infestation

means the presence in large numbers of a multiplying parasitic, or commensal, agent on a host so as to cause damage or *disease*.

The Community suggests that the word "aquatic" should be deleted in the proposed definition of "subpopulation" to make it identical with the definition in the Terrestrial Code

Subpopulation

means a distinct part of a *population* identifiable according to specific common *aquatic animal* health characteristics.

Veterinary para-professional

means a person who, for the purposes of the *Aquatic Code*, is authorised by the *veterinary statutory body* to carry out certain designated tasks (dependent upon the category of veterinary para-professional) in a country, and delegated to them under the responsibility and direction of a *veterinarian*. The tasks authorized for each category of *veterinary para-professional* should be defined by the *veterinary statutory body* depending on qualifications and training, and according to need.

Zoning

means identifying *zones* for disease control or *international trade* purposes.

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— text deleted

Appendix IV

CHAPTER 1.2.3.

DISEASES LISTED BY THE OIE

Community comment

The Community agrees with the proposed amendments. However, the Community raises a concern regarding the continuously increasing number of listed crustacean diseases and the relatively low number of notifications made by the OIE Member Countries.

Preamble: The following diseases are listed by the OIE according to the criteria for listing an aquatic animal disease (see Article 1.2.2.1.) or criteria for listing an emerging aquatic animal disease (see Article 1.2.2.2.)

Article 1.2.3.1.

The following diseases of fish are listed by the OIE:

- Epizootic haematopoietic necrosis
- Infectious haematopoietic necrosis
- Spring viraemia of carp
- Viral haemorrhagic septicaemia
- Infectious salmon anaemia
- Epizootic ulcerative syndrome
- Gyrodactylosis (*Gyrodactylus salaris*)
- Red sea bream iridoviral disease
- Koi herpesvirus disease.

Article 1.2.3.2.

The following diseases of molluscs are listed by the OIE:

- Infection with *Bonamia ostreae*
- Infection with *Bonamia exitiosa*
- Infection with *Marteilia refringens*
- Infection with *Perkinsus marinus*
- Infection with *Perkinsus olseni*

- Infection with *Xenohaliotis californiensis*.
- Abalone viral mortality ~~(1)~~.

Appendix IV (contd)

Article 1.2.3.3.

The following diseases of crustaceans are listed by the OIE:

- Taura syndrome
- White spot disease
- Yellowhead disease
- Tetrahedral baculovirosis (*Baculovirus penaei*)
- Spherical baculovirosis (*Penaeus monodon*-type baculovirus)
- Infectious hypodermal and haematopoietic necrosis
- Crayfish plague (*Aphanomyces astaci*)
- Necrotising hepatopancreatitis~~2~~
- Infectious myonecrosis~~2~~
- White tail disease (1)
- Hepatopancreatic parvovirus disease (1)
- Mourilyan virus disease (1).

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1 Listed according to Article 1.2.2.2.

~~2 Listing of this disease is under study.~~

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— text deleted

CHAPTER 1.4.4.

ZONING AND COMPARTMENTALISATION

Article 1.4.4.1.

Community comment

The Community can support this new chapter but would like to have its comments taken into account.

The Community encourages the OIE to establish, using this new chapter, the criteria to regain freedom for previously free infected compartments.

Introduction

Given the difficulty of establishing and maintaining for an entire country the status of *free country* for a particular *disease*, especially for *diseases* the entry of which is difficult to control through measures at national boundaries, there may be benefits to one or more Member Countries in establishing and maintaining a *subpopulation* with a distinct *aquatic animal health status*. *Subpopulations* may be separated by natural or artificial geographical barriers or, in certain situations, by the application of appropriate management systems.

Zoning and *compartmentalisation* are procedures implemented by a country under the provisions of this chapter with a view to defining *subpopulations* of distinct *aquatic animal health status* for the purpose of disease control or *international trade*. *Compartmentalisation* applies to a *subpopulation* when management practices related to biosecurity are the defining factors, while *zoning* applies when a *subpopulation* is defined on a geographical basis. In practice, spatial considerations and good management play important roles in the application of both concepts.

This chapter is to assist OIE Member Countries wishing to establish and maintain different *subpopulations*, using the principles of *compartmentalisation* and *zoning*. These principles should be applied in accordance with the measures recommended in the relevant *disease* chapter(s). This chapter also outlines a process through which trading partners may recognise such *subpopulations*. This process is best implemented by trading partners through establishing parameters and gaining agreement on the necessary measures prior to *outbreaks of disease*.

Before trade in *aquatic animals* or *aquatic animal products* may occur, an *importing country* needs to be satisfied that its *aquatic animal health status* will be appropriately protected. In most cases, the import regulations developed will rely in part on judgements made about the effectiveness of sanitary procedures undertaken by the *exporting country*, both at its borders and within its *territory*.

As well as contributing to the safety of *international trade*, *zoning* and *compartmentalisation* may assist *disease* control or eradication within Member Countries. *Zoning* may encourage the more efficient use of resources, and *compartmentalisation* may allow the functional separation of a *subpopulation* from other domestic or wild *aquatic animals* through biosecurity measures, which a *zone* (through geographical separation) would not achieve. Following an *outbreak of disease*, *compartmentalisation* may be able to take advantage of epidemiological links among *subpopulations* or common practices relating to biosecurity, despite diverse geographical locations, to facilitate *disease* control and/or the resumption of trade.

Zoning and *compartmentalisation* may not be applicable to all *diseases*, but separate requirements will be

developed for each *disease* for which the application of *zoning* or *compartmentalisation* is considered appropriate.

To regain the status of a *free zone* or *free compartment* following an *outbreak of disease,* Member Countries should follow the recommendations in the relevant disease chapter in the *Aquatic Code*.

Article 1.4.4.2.

Community comments

When establishing and maintaining the distinct aquatic animal health status of a zone or compartment, a key element is the risk of introduction of diseases in such zones or compartments. The Community proposes an addition to the 2nd paragraph of this article:

The procedures used to establish and maintain the distinct *aquatic animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances and will depend on the epidemiology of the *disease*, environmental factors, **risk of introduction of diseases** and applicable biosecurity measures. The *exporting country* should be able to demonstrate, through detailed documentation published through official channels, that it has implemented the recommendations in the *Aquatic Code* for establishing and maintaining such a *zone* or *compartment*.

General considerations

The *Competent Authority* of an *exporting country* that is establishing a *zone* or *compartment* for *international trade* purposes should clearly define the *subpopulation* in accordance with the recommendations in the relevant chapters in the *Aquatic Code,* including those on *surveillance*, and the identification and traceability of *aquatic animals*. The *Competent Authority* of an *exporting country* should be able to explain to the *Competent Authority* of an *importing country* the basis for its claim of a distinct *aquatic animal health status* for the *zone* or *compartment* in such terms.

The procedures used to establish and maintain the distinct *aquatic animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances and will depend on the epidemiology of the *disease*, environmental factors and applicable biosecurity measures. The *exporting country* should be able to demonstrate, through detailed documentation published through official channels, that it has implemented the recommendations in the *Aquatic Code* for establishing and maintaining such a *zone* or *compartment*.

An *importing country* should recognise the existence of this *zone* or *compartment* when the appropriate measures recommended in the *Aquatic Code* are applied, and the *Competent Authority* of the *exporting country* certifies that this is the case.

Where countries share a *zone* or *compartment*, the *Competent Authority* of each country should collaborate to define and fulfil their respective responsibilities.

Article 1.4.4.3.

Community comments:

This article is proposed to be deleted in the Terrestrial Code and included as a paragraph in the previous article. In our view, the same approach should be taken in the Aquatic Code

Prerequisite considerations in defining a zone or compartment

The *exporting country* should conduct an assessment of the resources needed and available to establish and maintain a *zone* or *compartment* for *international trade* purposes. These include the human and financial resources and the technical capability of the *Competent Authority* (and of the relevant industry, in the case of a *compartment*) including on *disease surveillance* and diagnosis.

Article 1.4.4.4.

Community comments:

As a first step when defining subpopulations, registration of all the aquaculture establishment made by the Competent Authority should take place. It is proposed the following addition to point 4
*For a zone or compartment, the Competent Authority should document in detail the measures taken to ensure the identification of the subpopulation**, for example by means of registration of all the aquaculture establishments located in such zone or compartment,** and maintenance of its aquatic animal health status through a biosecurity plan. The measures used to establish and maintain the distinct aquatic animal health status of a zone or compartment should be appropriate to the particular circumstances and will depend on the epidemiology of the disease, environmental factors, the aquatic animal health status in adjacent areas, applicable biosecurity measures (including movement controls, use of natural and artificial boundaries, the spatial separation of aquatic animals, and commercial management and husbandry practices), and surveillance.*

Although its main elements are included in this article, "Traceability" should be specifically mentioned in point 6 as it is one of the key concepts when defining a compartment. Furhtermore, audit and regular re-assessment of the compartment shall be emphasised in point 6 as an important part in the description of the bio-security plan in the way it is done in the Terrestrial Code. Accordingly, we suggest that the same sentence as in the Terrestrial Code is added at the end of point 6: "The *biosecurity plan* should also describe how the measures will be audited to ensure that the risks are regularly re-assessed and the measures adjusted accordingly". That is also in line with the definition of the biosecurity plan.

Principles for defining a zone or compartment

In conjunction with the above considerations and the definitions of *zone* and *compartment*, the following principles should apply when Member Countries define a *zone* or *compartment*:

1. The extent of a *zone* should be established by the *Competent Authority* on the basis of the definition of *zone* and made public through official channels.

2. The factors defining a *compartment* should be established by the *Competent Authority* on the basis of relevant criteria such as management and husbandry practices related to biosecurity, and made public through official channels.

3. *Aquatic animals* belonging to such *subpopulations* need to be recognizable as such through a clear epidemiological separation from other *aquatic animals* and all things presenting a *disease* risk.

4. For a *zone* or *compartment*, the *Competent Authority* should document in detail the measures taken to ensure the identification of the *subpopulation* and the establishment and maintenance of its *aquatic animal health status* through a *biosecurity plan*. The measures used to establish and maintain the distinct *aquatic animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances and will depend on the epidemiology of the *disease*, environmental factors, the *aquatic animal health status* in adjacent areas, applicable biosecurity measures (including movement controls, use of natural and artificial boundaries, the spatial separation of *aquatic animals*, and commercial management and husbandry practices), and *surveillance*.

5. For a *compartment*, the *biosecurity plan* should describe the partnership between the relevant enterprise/industry and the *Competent Authority,* and their respective responsibilities, including the procedures for oversight of the operation of the *compartment* by the *Competent Authority*.

6. For a *compartment*, the *biosecurity plan* should also describe the routine operating procedures to provide clear evidence that the *surveillance* conducted and the management practices are adequate to meet the

definition of the *compartment*. In addition to information on *aquatic animal* movements, the *biosecurity plan* should include production and stock records, feed sources, *surveillance* results, visitor logbook, morbidity and mortality history, medications, vaccinations, documentation of training and any other criteria necessary for evaluation of risk mitigation. The information required may vary according to the *aquatic animal* species and *disease(s)* under consideration.

7. Thus defined, the *zones* and *compartments* constitute the relevant *subpopulations* for the application of the recommendations in Part 2 of the *Aquatic Code*.

Article 1.4.4.5.

Sequence of steps to be taken in defining a zone/compartment and having it recognised for international trade purposes

There is no single sequence of steps which should be followed in defining a *zone* or a *compartment*. The steps that the *Competent Authority* of the *importing country* and the *exporting country* choose and implement will generally depend on the circumstances existing within the countries and at their borders, and their trading history. The recommended steps are:

1. For zoning

   a) The *exporting country* identifies a geographical area, which it considers to contain an *aquatic animal subpopulation* with a distinct *aquatic animal health status* with respect to a specific *disease*/specific *diseases*, based on *surveillance*.

   b) The *exporting country* describes in the *biosecurity plan* for the *zone* the measures which are being, or will be, applied to distinguish such an area epidemiologically from other parts of its *territory*, in accordance with the recommendations in the *Aquatic Code*.

   c) The *exporting country* provides the above information to the *importing country*, with an explanation of why the area can be treated as an epidemiologically separated *zone* for *international trade* purposes.

   d) The *importing country* determines whether it accepts such an area as a *zone* for the importation of *aquatic animals* and *aquatic animal products*, taking into account:

      i) an evaluation of the *exporting country*'s *Competent Authority*;

      ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;

      iii) its own *aquatic animal* health situation with respect to the *disease(s)* concerned; and

      iv) other relevant OIE standards.

   e) The *importing country* notifies the *exporting country* of the result of its determination and the underlying reasons, within a reasonable period of time, being either:

      i) recognition of the *zone*;

      ii) request for further information; or

      iii) rejection of the area as a *zone* for *international trade* purposes.

   f) An attempt should be made to resolve any differences over the definition of the *zone*, either in the interim or finally, by using an agreed mechanism to reach consensus (such as the OIE

dispute settlement mechanism).

g) The *importing country* and the *exporting country* may enter into a formal agreement defining the *zone*.

2. For compartmentalisation

a) Based on discussions with the relevant enterprise/industry, the *exporting country* identifies a *compartment* of one or more *aquaculture establishments* or other premises owned by an enterprise(s) which operates under common management practices related to biosecurity, and which contains an identifiable *aquatic animal subpopulation* with a distinct *aquatic animal health status* with respect to a specific *disease*/specific *diseases*; the *exporting country* describes how this status is maintained through a partnership between the relevant enterprise/industry and the *Competent Authority* of the *exporting country*.

b) The *exporting country* examines the *compartment's biosecurity plan* and confirms through an audit that:

i) the *compartment* is epidemiologically closed throughout its routine operating procedures as a result of effective implementation of its *biosecurity plan*; and

ii) the *surveillance* programme in place is appropriate to verify the status of such *aquaculture establishment(s)* with respect to such *disease(s)*.

c) The *exporting country* describes the *compartment*, in accordance with the recommendations in the *Aquatic Code*.

d) The *exporting country* provides the above information to the *importing country*, with an explanation of why such an enterprise can be treated as an epidemiologically separated *compartment* for *international trade* purposes.

e) The *importing country* determines whether it accepts such an enterprise as a *compartment* for the importation of *aquatic animals* and *aquatic animal products*, taking into account:

i) an evaluation of the *exporting country's Competent Authority*;

ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;

iii) its own *aquatic animal* health situation with respect to the *disease(s)* concerned; and

iv) other relevant OIE standards.

f) The *importing country* notifies the *exporting country* of the result of its examination and the underlying reasons, within a reasonable period of time, being either:

i) recognition of the *compartment*;

ii) request for further information; or

iii) rejection of such an enterprise as a *compartment* for *international trade* purposes.

g) An attempt should be made to resolve any differences over the definition of the *compartment*, either in the interim or finally, by using an agreed mechanism to reach consensus (such as the OIE dispute settlement mechanism).

h) The *importing country* and the *exporting country* may enter into a formal agreement defining the *compartment*.

CHAPTER 2.2.1.

INFECTION WITH *BONAMIA OSTREAE*

Community comments

The community agrees with the proposed chapter, but would ask the OIE to consider the comments included under the specific Articles.

Article 2.2.1.1.

For the purposes of the *Aquatic Code*, infection with *Bonamia ostreae* means *infection* only with *Bonamia ostreae*.

Methods for surveillance, diagnosis and confirmatory identification are provided in the *Aquatic Manual*.

Article 2.2.1.2.

Scope

The recommendations in this Chapter apply to: European flat oyster (*Ostrea edulis*), Australian mud oyster (*O. angasi*), Argentinean flat oyster (*O. puelchana*), Chilean flat oyster (*O. chilensis*), Asiatic oyster (*O. denselammellosa*) and Suminoe oyster (*Crassostrea ariakensis*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 2.2.1.3.

Community comment

The Community agrees with point 1 of this article but would like the inclusion in point 1a) of the following commodity "biological samples preserved for diagnostic applications in such a manner as to inactivate *Bonamia ostreae*" as this wording is included in the crustacean chapters.

The Community would like to have further clarification with regard to the maintenance of "larvae" under point 1). To our best knowledge, there is no scientific evidence that probes that larvae could be considered as safe commodities for mollusc infections which can be transmitted directly (Infections with *Bonamia ostreae, B. exitiosa* and *Mikrocytos mackini.*

Some recent studies based on the use of molecular tools, revealed infection with *Bonamia ostreae* in less than 6 month old spat (Lynch et al. 2005) Thus we think that, generally, we lack such recent studies (using molecular tools) concerning young bivalves stages (including larvae) regarding their sensitivity to these listed diseases and we consider that unless we have such studies done, "larvae" need to be deleted from point 1. This request is also reinforced by the fact that larvae produced in hatchery are submitted to transfer to nurseries or the field and thus present some high risk of disease transmission.

Lynch SA, Armitage DV, Wylde S, Mulcahy MF, Culloty SC (2005) The susceptibility of young prespawning oysters, Ostrea edulis, to Bonamia ostreae,. Journal of Shellfish Research 24:1019-1025

The Community would propose an alternative wording to point 1c) to avoid the accidental contamination of consignments of *Crassostrea gigas*, *C. virginica*, *Ruditapes decussatus*, *R. philippinarum*, *Mytilus galloprovincialis* and *M. edulis* with animals of other non-safe species. Point 1.c) should read:

All *commodities* containing animals only from the following species *Crassostrea gigas*, *C. virginica*, *Ruditapes decussatus*, R. *philippinarum*, *Mytilus galloprovincialis* and *M. edulis*, including the live *aquatic animal.*

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any *Bonamia ostreae* related conditions, regardless of the *Bonamia ostreae* status of the *exporting country*, *zone* or *compartment*:

   a) For the species referred to in Article 2.2.1.2. for any purpose:

      i) commercially sterile canned or other heat treated products;

      ii) ~~*gametes*, *eggs* and~~ larvae.

   b) The following *commodities* destined for human consumption from the species referred to in Article 2.2.1.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:

      i) chemically preserved products (e.g. smoked, salted, pickled, marinated~~, etc.~~);

      ii) non commercially sterile products (e.g. ready prepared meals) that have been heat treated in a manner to ensure the inactivation of the parasite;

      iii) off the shell (chilled or frozen) packaged for direct retail trade;

      iv) half-shell (chilled).

   c) All *commodities* from *Crassostrea gigas*, *C. virginica*, *Ruditapes decussatus*, *R. philippinarum*, *Mytilus galloprovincialis* and *M. edulis*, including the live *aquatic animal.*

   For the *commodities* referred to in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of *commodities* of a species referred to in Article 2.2.1.2., other than *commodities* referred to in point 1 of Article 2.2.1.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.2.1.7. to 2.2.1.11. relevant to the *Bonamia ostreae* status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of any other *commodity* from bivalve species not referred to in Article 2.2.1.2. (especially those of the genus *Ostrea*) ~~n~~or in point 1c) of Article 2.2.1.3., from an *exporting country*, *zone* or *compartment* not declared free of *Bonamia ostreae*, the *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *Bonamia ostreae*, and the potential consequences, associated with the importation of the *commodity* prior to a decision. The *exporting country* should be informed of the outcome of this assessment.

Article 2.2.1.4.

***Bonamia ostreae* free country**

Community comment

The Community would like to have further clarification with regard to the maintenance of different biosecurity conditions timeframes in the different mollusc chapters.

The Community would argue that option 2 is irrelevant for freedom from *B. ostreae*. According to recent outbreaks in previously free Community Members, a B. ostreae free Country, cannot be declared free without a carefully planned targeted surveillance scheme.

A country may make a *self-declaration of freedom* from *Bonamia ostreae* if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from *Bonamia ostreae* if all the areas covered by the shared water are declared *Bonamia ostreae* free *zones* (see Article 2.2.1.5.).

1. A country where none of the *susceptible species* referred to in Article 2.2.1.2. is present may make a *self-declaration of freedom* from *Bonamia ostreae* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where any *susceptible species* referred to in Article 2.2.1.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.1. of the *Aquatic Manual*, may make a *self-declaration of freedom* from *Bonamia ostreae* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years and infection with *Bonamia ostreae* is not known to be established in wild populations.

OR

3. A country where the last known clinical occurrence was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to clinical expression, as described in Chapter 2.2.1. of the *Aquatic Manual*, may make a *self-declaration of freedom* from *Bonamia ostreae* when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.1. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Bonamia ostreae*.

OR

4. A country that has made a *self-declaration of freedom* from *Bonamia ostreae* but in which the *disease* is detected may not make a *self-declaration of freedom* from *Bonamia ostreae* again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.1. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Bonamia ostreae*.

In the meantime, part of the non-affected area may be declared a free *zone* provided that it meets the conditions in point 3 of Article 2.2.1.5.

Article 2.2.1.5.

The Community would like to have further clarification with regard to the maintenance different biosecurity conditions timeframes in the different mollusc chapters

The Community would argue that option 2 is irrelevant for freedom from *B. ostreae*. According to recent outbreaks in previously free Community zones or compartments , a B. ostreae free zone or compartment, cannot be declared free without a carefully planned targeted surveillance scheme.

The Community raises a concern on how to deal with intermediate hosts, if any, when regaining the freedom satus in zone or compartments according to point 4.

***Bonamia ostreae* free zone or free compartment**

A *zone* or *compartment* free from *Bonamia ostreae* may be established within the *territory* of one or more countries of infected or unknown status for infection with *Bonamia ostreae* and declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a *Bonamia ostreae* free *zone* or *compartment* if the conditions outlined below apply to all areas of the *zone* or *compartment*.

1. In a country of unknown status for *Bonamia ostreae*, a *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.2.1.2. is present may be declared free from *Bonamia ostreae* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. In a country of unknown status for *Bonamia ostreae*, a *zone* or *compartment* where any *susceptible species* referred to in Article 2.2.1.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.1. of the *Aquatic Manual*, may be declared free from *Bonamia ostreae* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years and infection with *Bonamia ostreae* is not known to be established in wild populations.

OR

3. A *zone* or *compartment* where the last known clinical occurrence was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of

conditions conducive to clinical expression, as described in Chapter 2.2.1. of the *Aquatic Manual*, may be declared free from *Bonamia ostreae* when:

a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.1. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Bonamia ostreae*.

OR

4. A *zone* previously declared free from *Bonamia ostreae* but in which the *disease* is detected may not be declared free from *Bonamia ostreae* again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.1. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Bonamia ostreae*.

Article 2.2.1.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *Bonamia ostreae* following the provisions of points 1 or 2 of Articles 2.2.1.4. or 2.2.1.5. (as relevant) may maintain its status as *Bonamia ostreae* free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *Bonamia ostreae* following the provisions of point 3 of Articles 2.2.1.4. or 2.2.1.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as *Bonamia ostreae* free provided that conditions that are conducive to clinical expression of infection with *Bonamia ostreae*, as described in Chapter 2.2.1. of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of infection with *Bonamia ostreae*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.2.1.7.

Importation of live aquatic animals from a country, zone or compartment declared free from *Bonamia ostreae*

When importing live *aquatic animals* of species referred to in Article 2.2.1.2. from a country, *zone* or *compartment* declared free from *Bonamia ostreae*, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.1.4. or 2.2.1.5. (as applicable), whether the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from *Bonamia ostreae*.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.2.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.1.3.

Article 2.2.1.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from *Bonamia ostreae*

Community comment

The Community would suggest the OIE that, in order to improve the animal health guarantees applicable to this commodities the words"appropriate period of time" are added to point 1. Point 1 would then read:

the direct delivery into and holding of the consignment in *quarantine* facilities during an appropriate period of time;

When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.2.1.2. from a country, *zone* or *compartment* not declared free from *Bonamia ostreae*, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the direct delivery into and holding of the consignment in *quarantine* facilities;

2. the continuous isolation of the imported *aquatic animals* from the local environment;

3. the treatment of all effluent and waste material from the processing in a manner that ensures inactivation of *Bonamia ostreae*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.1.3.

Article 2.2.1.9.

Importation of live aquatic animals for processing for human consumption from a country, zone or compartment not declared free from *Bonamia ostreae*

Community comment

In the ingress the wording from "should require" should be amended to read "should assess the risk and apply risk mitigation such as".

This represents a more flexible approach- while still securing an appropriate level of protection, and is preferred by the Community. If this proposal is not acceptable, the word "should", should be replaced by "may".

When importing, for processing for human consumption, live *aquatic animals* of species referred to in Article 2.2.1.2. from a country, *zone* or *compartment* not declared free from *Bonamia ostreae*, the *Competent Authority* of the *importing country* should require that:

1. the consignment be delivered directly to and held in *quarantine* facilities until processing and/or consumption; and

2. all effluent and waste material from the processing be treated in a manner that ensures inactivation of *Bonamia ostreae*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.1.3.

Article 2.2.1.10.

Community comment

The recommendation in article 2.2.1.10. seems inconsistent taking into account the definition of aquatic animals products (non-viable aquatic animals and products from aquatic animals), when this article is compared with article 2.2.1.9. To request animal health certificates for non-viable molluscs or molluscs products, taking into account their intended use and the nature of the commodities (which by nature cannot be for further farming), seems non-justifiable.

The Community would suggest the OIE to merge article 2.2.1.10 with article 2.2.1.11. The new article would read:

Importation of aquatic animal products

When importing *aquatic animal products* of species referred to in Article 2.2.1.2., the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.1.3.

Importation of aquatic animal products from a country, zone or compartment declared free from *Bonamia ostreae*

When importing *aquatic animal products* of species referred to in Article 2.2.1.2. from a country, *zone* or *compartment* declared free from *Bonamia ostreae*, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.1.4. or 2.2.1.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Bonamia ostreae*.

The *certificate* should be in accordance with the Model Certificate in Appendix X.X.X. (under study).

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.1.3.

Article 2.2.1.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from *Bonamia ostreae*

When importing *aquatic animal products* of species referred to in Article 2.2.1.2. from a country, *zone* or *compartment* not declared free from *Bonamia ostreae*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.1.3.

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CHAPTER 2.2.2.

INFECTION WITH *BONAMIA EXITIOSA*

Community comments

The community agrees with the proposed chapter, but would ask the OIE to consider the comments included under the specific Articles.

Article 2.2.2.1.

For the purposes of the *Aquatic Code*, infection with *Bonamia exitiosa* means *infection* only with *Bonamia exitiosa*.

Methods for surveillance, diagnosis and confirmatory identification are provided in the *Aquatic Manual*.

Article 2.2.2.2.

Scope

The recommendations in this Chapter apply to: Australian mud oyster (*Ostrea angasi*) and Chilean flat oyster (*O. chilensis*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 2.2.2.3.

Community comment

The Community agrees with point 1 of this article but would like the inclusion in point 1a) of the following commodity "biological samples preserved for diagnostic applications in such a manner as to inactivate *Bonamia exitiosa*" as this wording is included in the crustacean chapters.

The Community would like to have further clarification with regard to the maintenance of "larvae" under point 1). To our best knowledge, there is no scientific evidence that probes that larvae could be considered as safe commodities for mollusc infections which can be transmitted directly (Infections with *Bonamia ostreae, B. exitiosa* and *Mikrocytos mackini).*

The Community would propose an alternative wording to point 1c) to avoid the accidental contamination of consignments of *Crassostrea gigas and Saccostrea glomerata* with animals of other non-safe species. Point 1.c) should read:

All *commodities* containing animals only from the following species *Crassostrea gigas* and *Saccostrea glomerata* including the live *aquatic animal*.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any *Bonamia exitiosa* related conditions, regardless of the *Bonamia exitiosa* status of the *exporting country*, *zone* or *compartment*:

   a) For the species referred to in Article 2.2.2.2. for any purpose:

      i) commercially sterile canned or other heat treated products;

      ii) ~~*gametes*, *eggs* and~~ larvae.

   b) The following *commodities* destined for human consumption from the species referred to in Article 2.2.2.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:

      i) chemically preserved products (e.g. smoked, salted, pickled, marinated~~, etc.~~);

      ii) non commercially sterile products (e.g. ready prepared meals) that have been heat treated in a manner to ensure the inactivation of the parasite;

      iii) off the shell (chilled or frozen) packaged for direct retail trade;

      iv) half-shell (chilled).

   c) All *commodities* from *Crassostrea gigas*~~, *C. virginica*~~ and *Saccostrea glomerata*, including the live *aquatic animal*.

   For the *commodities* referred to in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of *commodities* of a species referred to in Article 2.2.2.2., other than *commodities* referred to in point 1 of Article 2.2.2.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.2.2.7. to 2.2.2.11. relevant to the *Bonamia exitiosa* status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of any other *commodity* from bivalve species not referred to in Article 2.2.2.2. (especially those of the genus *Ostrea*) ~~n~~or in point 1c) of Article 2.2.2.3., from an *exporting country*, *zone* or *compartment* not declared free of *Bonamia exitiosa*, the *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *Bonamia exitiosa*, and the potential consequences, associated with the importation of the *commodity* prior to a decision. The *exporting country* should be informed of the outcome of this assessment.

Article 2.2.2.4.

Community comment

The Community would like to have further clarification with regard to the maintenance of different biosecurity conditions timeframes in the different mollusc chapters

***Bonamia exitiosa* free country**

A country may make a *self-declaration of freedom* from *Bonamia exitiosa* if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from *Bonamia exitiosa* if all the areas covered by the shared water are declared *Bonamia exitiosa* free *zones* (see Article 2.2.2.5.).

1. A country where none of the *susceptible species* referred to in Article 2.2.2.2. is present may make a *self-declaration of freedom* from *Bonamia exitiosa* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where any *susceptible species* referred to in Article 2.2.2.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.2. of the *Aquatic Manual*, may make a *self-declaration of freedom* from *Bonamia exitiosa* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years and infection with *Bonamia exitiosa* is not known to be established in wild populations.

OR

3. A country where the last known clinical occurrence was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to clinical expression, as described in Chapter 2.2.2. of the *Aquatic Manual*, may make a *self-declaration of freedom* from *Bonamia exitiosa* when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.2. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Bonamia exitiosa*.

OR

4. A country that has made a *self-declaration of freedom* from *Bonamia exitiosa* but in which the *disease* is detected may not make a *self-declaration of freedom* from *Bonamia exitiosa* again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.2. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Bonamia exitiosa*.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that it meets the conditions in point 3 of Article 2.2.2.5.

Article 2.2.2.5.

The Community would like to have further clarification with regard to the maintenance different biosecurity conditions timeframes in the different mollusc chapters

The Community raises a concern on how to deal with intermediate hosts, if any, when regaining the freedom satus in zone or compartments according to point 4.

Bonamia exitiosa free zone or free compartment

A *zone* or *compartment* free from *Bonamia exitiosa* may be established within the *territory* of one or more countries of infected or unknown status for infection with *Bonamia exitiosa* and declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a *Bonamia exitiosa* free *zone* or *compartment* if the conditions outlined below apply to all areas of the *zone* or *compartment*.

1. In a country of unknown status for *Bonamia exitiosa*, a *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.2.2.2. is present may be declared free from *Bonamia exitiosa* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. In a country of unknown status for *Bonamia exitiosa*, a *zone* or *compartment* where any *susceptible species* referred to in Article 2.2.2.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.2. of the *Aquatic Manual*, may be declared free from *Bonamia exitiosa* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years and infection with *Bonamia exitiosa* is not known to be established in wild populations.

OR

3. A *zone* or *compartment* where the last known clinical occurrence was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to clinical expression, as described in Chapter 2.2.2. of the *Aquatic Manual*, may be declared free from *Bonamia exitiosa* when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.2. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Bonamia exitiosa*.

OR

4. A *zone* previously declared free from *Bonamia exitiosa* but in which the *disease* is detected may not be declared free from *Bonamia exitiosa* again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.2. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Bonamia exitiosa*.

Article 2.2.2.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *Bonamia exitiosa* following the provisions of points 1 or 2 of Articles 2.2.2.4. or 2.2.2.5. (as relevant) may maintain its status as *Bonamia exitiosa* free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *Bonamia exitiosa* following the provisions of point 3 of Articles 2.2.2.4. or 2.2.2.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as *Bonamia exitiosa* free provided that conditions that are conducive to clinical expression of infection with *Bonamia exitiosa*, as described in Chapter 2.2.2. of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of infection with *Bonamia exitiosa*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.2.2.7.

Importation of live aquatic animals from a country, zone or compartment declared free from *Bonamia exitiosa*

When importing live *aquatic animals* of species referred to in Article 2.2.2.2. from a country, *zone* or *compartment* declared free from *Bonamia exitiosa*, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.2.4. or 2.2.2.5. (as applicable), whether the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from *Bonamia exitiosa*.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.2.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.2.3.

Article 2.2.2.8

. **Community comment**

The Community would suggest the OIE that, in order to improve the animal health guarantees applicable to this commodities the words"appropriate period of time" are added to point 1. Point 1 would then read:

the direct delivery into and holding of the consignment in *quarantine* facilities during an appropriate period of time;

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from *Bonamia exitiosa*

When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.2.2.2. from a country, *zone* or *compartment* not declared free from *Bonamia exitiosa*, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the direct delivery into and holding of the consignment in *quarantine* facilities;

2. the continuous isolation of the imported *aquatic animals* from the local environment;

3. the treatment of all effluent and waste material from the processing in a manner that ensures inactivation of *Bonamia exitiosa*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.2.3.

Article 2.2.2.9.

Community comment

In the ingress the wording from "should require" should be amended to read "should assess the risk and apply risk mitigation such as".

This represents a more flexible approach- while still securing a appropriate level of protection, and is preferred by the Community. If this proposal is not acceptable, the word "should", should be replaced by "may".

Importation of live aquatic animals for processing for human consumption from a country, zone or compartment not declared free from *Bonamia exitiosa*

When importing, for processing for human consumption, live *aquatic animals* of species referred to in Article 2.2.2.2. from a country, *zone* or *compartment* not declared free from *Bonamia exitiosa*, the *Competent Authority* of the *importing country* should require that:

1. the consignment be delivered directly to and held in *quarantine* facilities until processing and/or consumption; and

2. all effluent and waste material from the processing be treated in a manner that ensures inactivation of *Bonamia exitiosa*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.2.3.

Article 2.2.2.10.

Community comment

The recommendation in article 2.2.2.10. seems inconsistent taking into account the definition of aquatic animals products (non-viable aquatic animals and products from aquatic animals), when this article is compared with article 2.2.2.9. To request animal health certificates for non-viable molluscs or molluscs products, taking into account their intended use and the nature of the commodities (which by nature cannot be for further farming), seems non-justifiable

The Community would suggest the OIE to merge article 2.2.2.10 with article 2.2.2.11. The new article would read:

Importation of aquatic animal products

When importing *aquatic animal products* of species referred to in Article 2.2.2.2., the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.2.3.

Importation of aquatic animal products from a country, zone or compartment declared free from *Bonamia exitiosa*

When importing *aquatic animal products* of species referred to in Article 2.2.2.2. from a country, *zone* or *compartment* declared free from *Bonamia exitiosa*, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.2.4. or 2.2.2.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Bonamia exitiosa*.

The *certificate* should be in accordance with the Model Certificate in Appendix X.X.X. (under study).

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.2.3.

Article 2.2.2.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from *Bonamia exitiosa*

When importing *aquatic animal products* of species referred to in Article 2.2.2.2. from a country, *zone* or *compartment* not declared free from *Bonamia exitiosa*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.2.3.

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CHAPTER 2.2.3.

INFECTION WITH *HAPLOSPORIDIUM NELSONI*

Community comments

The community agrees with the proposed chapter, but would ask the OIE to consider the comments included under the specific Articles.

Article 2.2.3.1.

For the purposes of the *Aquatic Code*, infection with *Haplosporidium nelsoni* means *infection* only with *Haplosporidium nelsoni*.

Methods for surveillance, diagnosis and confirmatory identification are provided in the *Aquatic Manual* (under study).

Article 2.2.3.2.

Scope

The recommendations in this Chapter apply to: Pacific oyster (*Crassostrea gigas*) and Eastern oyster (*C. virginica*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 2.2.3.3.

Community comment

The Community agrees with point 1 of this article but would like the inclusion in point 1a) of the following commodity "biological samples preserved for diagnostic applications in such a manner as to inactivate *Haplosporidium nelsoni*" as this wording is included in the crustacean chapters.

The Community would like to have further clarification with regard to the maintenance of "larvae" under point 1).

The Community would propose an alternative wording to point 1c) to avoid the accidental contamination of consignments of *Crassostrea ariakensis* with animals of other non-safe species. Point 1.c) should read:

All *commodities* containing animals only from the following species *Crassostrea ariakensis,* including the live *aquatic animal.*

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any *Haplosporidium nelsoni* related conditions, regardless of the *Haplosporidium nelsoni* status of the *exporting country*, *zone* or *compartment*:

a) For the species referred to in Article 2.2.3.2. for any purpose:

i) commercially sterile canned or cooked products;

ii) ~~*gametes*, *eggs* and~~ larvae.

b) The following *commodities* destined for human consumption from the species referred to in Article 2.2.3.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:

i) chemically preserved products (e.g. smoked, salted, pickled, marinated~~, etc.~~);

ii) products (e.g. ready prepared meals) that have been heat treated in a manner to ensure the inactivation of the parasite;

iii) off the shell (chilled or frozen) packaged for direct retail trade;

iv) half-shell (chilled).

c) All *commodities* from *Crassostrea ariakensis*, including the live *aquatic animal*.

For the *commodities* referred to in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 2.2.3.2., other than *commodities* referred to in point 1 of Article 2.2.3.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.2.3.7. to 2.2.3.11. relevant to the *Haplosporidium nelsoni* status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of any other *commodity* from bivalve species not referred to in Article 2.2.3.2. ~~n~~or in point 1c) of Article 2.2.3.3., from an *exporting country*, *zone* or *compartment* not declared free of *Haplosporidium nelsoni*, the *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *Haplosporidium nelsoni*, and the potential consequences, associated with the importation of the *commodity* prior to a decision. The *exporting country* should be informed of the outcome of this assessment.

Article 2.2.3.4.

Community comment

The Community would like to have further clarification with regard to the maintenance of different biosecurity conditions timeframes in the different mollusc chapters

***Haplosporidium nelsoni* free country**

A country may make a *self-declaration of freedom* from *Haplosporidium nelsoni* if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from *Haplosporidium nelsoni* if all the areas covered by the shared water are declared *Haplosporidium nelsoni* free *zones* (see Article 2.2.3.5.).

1. A country where none of the *susceptible species* referred to in Article 2.2.3.2. is present may make a *self-declaration of freedom* from *Haplosporidium nelsoni* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where any *susceptible species* referred to in Article 2.2.3.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.3. of the *Aquatic Manual*, may make a *self-declaration of freedom* from *Haplosporidium nelsoni* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years and infection with *Haplosporidium nelsoni* is not known to be established in wild populations.

OR

3. A country where the last known clinical occurrence was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to clinical expression, as described in Chapter 2.2.3. of the *Aquatic Manual*, may make a *self-declaration of freedom* from *Haplosporidium nelsoni* when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.3. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Haplosporidium nelsoni*.

OR

4. A country that has made a *self-declaration of freedom* from *Haplosporidium nelsoni* but in which the *disease* is detected may not make a *self-declaration of freedom* from *Haplosporidium nelsoni* again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.3. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Haplosporidium nelsoni*.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that it meets the conditions in point 3 of Article 2.2.3.5.

Article 2.2.3.5.

The Community would like to have further clarification with regard to the maintenance different biosecurity conditions timeframes in the different mollusc chapters

The Community raises a concern on how to deal with intermediate hosts, if any, when regaining the freedom satus in zone or compartments according to point 4.

***Haplosporidium nelsoni* free zone or free compartment**

A *zone* or *compartment* free from *Haplosporidium nelsoni* may be established within the *territory* of one or more countries of infected or unknown status for infection with *Haplosporidium nelsoni* and declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a *Haplosporidium nelsoni* free *zone* or *compartment* if the conditions outlined below apply to all areas of the *zone* or *compartment*.

1. In a country of unknown status for *Haplosporidium nelsoni*, a *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.2.3.2. is present may be declared free from *Haplosporidium nelsoni* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. In a country of unknown status for *Haplosporidium nelsoni*, a *zone* or *compartment* where any species referred to in Article 2.2.3.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.3. of the *Aquatic Manual*, may be declared free from *Haplosporidium nelsoni* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years and infection with *Haplosporidium nelsoni* is not known to be established in wild populations.

OR

3. A *zone* or *compartment* where the last known clinical occurrence was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to clinical expression, as described in Chapter 2.2.3. of the *Aquatic Manual*, may be declared free from *Haplosporidium nelsoni* when:

    a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

    b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.3. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Haplosporidium nelsoni*.

OR

4. A *zone* previously declared free from *Haplosporidium nelsoni* but in which the *disease* is detected may not be declared free from *Haplosporidium nelsoni* again until the following conditions have been met:

    a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

    b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

    c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.3. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Haplosporidium nelsoni*.

Article 2.2.3.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *Haplosporidium nelsoni* following the provisions of points 1 or 2 of Articles 2.2.3.4. or 2.2.3.5. (as relevant) may maintain its status as *Haplosporidium nelsoni* free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *Haplosporidium nelsoni* following the provisions of point 3 of Articles 2.2.3.4. or 2.2.3.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as *Haplosporidium nelsoni* free provided that conditions that are conducive to clinical expression of infection with *Haplosporidium nelsoni*, as described in Chapter 2.2.3. of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of infection with *Haplosporidium nelsoni*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.2.3.7.

Importation of live aquatic animals from a country, zone or compartment declared free from *Haplosporidium nelsoni*

When importing live *aquatic animals* of species referred to in Article 2.2.3.2. from a country, *zone* or *compartment* declared free from *Haplosporidium nelsoni*, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.3.4. or 2.2.3.5. (as applicable), whether the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from *Haplosporidium nelsoni*.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.2.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.3.3.

Article 2.2.3.8.

Community comment

The Community would suggest the OIE that, in order to improve the animal health guarantees applicable to this commodities the words"appropriate period of time" are added to point 1. Point 1 would then read:

the direct delivery into and holding of the consignment in *quarantine* facilities during an appropriate period of time;

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from *Haplosporidium nelsoni*

When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.2.3.2. from a country, *zone* or *compartment* not declared free from *Haplosporidium nelsoni*, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the direct delivery into and holding of the consignment in *quarantine* facilities;

2. the continuous isolation of the imported *aquatic animals* from the local environment;

3. the treatment of all effluent and waste material from the processing in a manner that ensures inactivation of *Haplosporidium nelsoni*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.3.3.

Article 2.2.3.9.

. Community comment

In the ingress the wording from "should require" should be amended to read "should assess the risk and apply risk mitigation such as".

This represents a more flexible approach- while still securing an appropriate level of protection, and is preferred by the Community. If this proposal is not acceptable, the word "should", should be replaced by "may".

Importation of live aquatic animals for processing for human consumption from a country, zone or compartment not declared free from *Haplosporidium nelsoni*

When importing, for processing for human consumption, live *aquatic animals* of species referred to in Article 2.2.3.2. from a country, *zone* or *compartment* not declared free from *Haplosporidium nelsoni*, the *Competent Authority* of the *importing country* should require that:

1. the consignment be delivered directly to and held in *quarantine* facilities until processing and/or consumption; and

2. all effluent and waste material from the processing be treated in a manner that ensures inactivation of *Haplosporidium nelsoni*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.3.3.

Article 2.2.3.10.

Community comment

The recommendation in article 2.2.3.10. seems inconsistent taking into account the definition of aquatic animals products (non-viable aquatic animals and products from aquatic animals), when this article is compared with article 2.2.3.9. To request animal health certificates for non-viable molluscs or molluscs products, taking into account their intended use and the nature of the commodities (which by nature cannot be for further farming), seems non-justifiable

The Community would suggest the OIE to merge article 2.2.3.10 with article 2.2.3.11. The new article would read:

Importation of aquatic animal products

When importing *aquatic animal products* of species referred to in Article 2.2.3.2., the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.3.3.

Importation of aquatic animal products from a country, zone or compartment declared free from *Haplosporidium nelsoni*

When importing *aquatic animal products* of species referred to in Article 2.2.3.2. from a country, *zone* or *compartment* declared free from *Haplosporidium nelsoni*, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.3.4. or 2.2.3.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Haplosporidium nelsoni*.

The *certificate* should be in accordance with the Model Certificate in Appendix X.X.X. (under study).

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.3.3.

Article 2.2.3.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from *Haplosporidium nelsoni*

When importing *aquatic animal products* of species referred to in Article 2.2.3.2. from a country, *zone* or *compartment* not declared free from *Haplosporidium nelsoni*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.3.3.

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CHAPTER 2.2.4.

INFECTION WITH *MARTEILIA REFRINGENS*

Community comments

The Community agrees with the proposed chapter, but would ask the OIE to consider the comments included under the specific Articles.

Article 2.2.4.1.

For the purposes of the *Aquatic Code*, infection with *Marteilia refringens* means *infection* only with *Marteilia refringens*.

Methods for surveillance, diagnosis and confirmatory identification are provided in the *Aquatic Manual*.

Article 2.2.4.2.

Scope

The recommendations in this Chapter apply to: European flat oyster (*Ostrea edulis*), Australian mud oyster (*O. angasi*), Argentinean oyster (*O. puelchana*) and Chilean flat oyster (*O. chilensis*), ~~as well as~~ blue mussel (*Mytilus edulis*) and Mediterranean mussel (*M. galloprovincialis*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 2.2.4.3.

Community comment

The Community agrees with point 1 of this article but would like the inclusion in point 1a) of the following commodity "biological samples preserved for diagnostic applications in such a manner as to inactivate *Marteilia refringens*" as this wording is included in the crustacean chapters.

The Community would like to have further clarification with regard to the maintenance of "larvae" under point 1).

The Community would propose an alternative wording to point 1c) to avoid the accidental contamination of consignments of *Crassostrea gigas* with animals of other non-safe species. Point 1.c) should read:

All *commodities* containing animals only from the species *Crassostrea gigass,* including the live *aquatic animal.*

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any *Marteilia refringens* related conditions, regardless of the *Marteilia refringens* status of the *exporting country*, *zone* or *compartment*:

a) For the species referred to in Article 2.2.4.2. for any purpose:

i) commercially sterile canned or other heat treated products;

ii) ~~*gametes*, *eggs* and~~ larvae.

b) The following *commodities* destined for human consumption from the species referred to in Article 2.2.4.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:

i) chemically preserved products (e.g. smoked, salted, pickled, marinated~~, etc.~~);

ii) non commercially sterile products (e.g. ready prepared meals) that have been heat treated in a manner to ensure the inactivation of the parasite;

iii) off the shell (chilled or frozen) packaged for direct retail trade;

iv) half-shell (chilled).

c) All *commodities* from *Crassostrea gigas*, including the live *aquatic animal*.

For the *commodities* referred to in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of *commodities* of a species referred to in Article 2.2.4.2., other than *commodities* referred to in point 1 of Article 2.2.4.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.2.4.7. to 2.2.4.11. relevant to the *Marteilia refringens* status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of any other *commodity* from bivalve species not referred to in Article 2.2.4.2. (especially ~~those~~ the other species of the genera *Ostrea* and *Mytilus*) ~~n~~or in point 1c) of Article 2.2.4.3., from an *exporting country*, *zone* or *compartment* not declared free of *Marteilia refringens*, the *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *Marteilia refringens*, and the potential consequences, associated with the importation of the *commodity* prior to a decision. The *exporting country* should be informed of the outcome of this assessment.

Article 2.2.4.4.

Community comment

The Community would like to have further clarification with regard to the maintenance of different biosecurity conditions timeframes in the different mollusc chapters

***Marteilia refringens* free country**

A country may make a *self-declaration of freedom* from *Marteilia refringens* if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from *Marteilia refringens* if all the areas covered by the shared water are declared *Marteilia refringens* free *zones* (see Article 2.2.4.5.).

1. A country where none of the *susceptible species* referred to in Article 2.2.4.2. is present may make a *self-declaration of freedom* from *Marteilia refringens* when *basic biosecurity conditions* have been met continuously in the country for at least the past 3 years.

OR

2. A country where any *susceptible species* referred to in Article 2.2.4.2. is present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.4. of the *Aquatic Manual*, may make a *self-declaration of freedom* from *Marteilia refringens* when *basic biosecurity conditions* have been met continuously in the country for at least the past 3 years and infection with *Marteilia refringens* is not known to be established in wild populations.

OR

3. A country where the last known clinical occurrence was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to clinical expression, as described in Chapter 2.2.4. of the *Aquatic Manual*, may make a *self-declaration of freedom* from *Marteilia refringens* when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 3 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.4. of the *Aquatic Manual*, has been in place for at least the last 2 of the past 3 years without detection of *Marteilia refringens*.

OR

4. A country that has made a *self-declaration of freedom* from *Marteilia refringens* but in which the *disease* is detected may not make a *self-declaration of freedom* from *Marteilia refringens* again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.4. of the *Aquatic Manual*, has been in place for at least the last 2 of the past 3 years without detection of *Marteilia refringens*.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that it meets the conditions in point 3 of Article 2.2.4.5.

Article 2.2.4.5.

The Community would like to have further clarification with regard to the maintenance different biosecurity conditions timeframes in the different mollusc chapters

. The Community raises a concern on how to deal with intermediate hosts, if any, when regaining the freedom satus in zone or compartments according to point 4.

***Marteilia refringens* free zone or free compartment**

A *zone* or *compartment* free from *Marteilia refringens* may be established within the *territory* of one or more countries of infected or unknown status for infection with *Marteilia refringens* and declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a *Marteilia refringens* free *zone* or *compartment* if the conditions outlined below apply to all areas of the *zone* or *compartment*.

1. In a country of unknown status for *Marteilia refringens*, a *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.2.4.2. is present may be declared free from *Marteilia refringens* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 3 years.

OR

2. In a country of unknown status for *Marteilia refringens*, a *zone* or *compartment* where any *susceptible species* referred to in Article 2.2.4.2. is present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.4. of the *Aquatic Manual*, may be declared free from *Marteilia refringens* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 3 years and infection with *Marteilia refringens* is not known to be established in wild populations.

OR

3. A *zone* or *compartment* where the last known clinical occurrence was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to clinical expression, as described in Chapter 2.2.4. of the *Aquatic Manual*, may be declared free from *Marteilia refringens* when:

    a) *basic biosecurity conditions* have been met continuously for at least the past 3 years; and

    b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.4. of the *Aquatic Manual*, has been in place for at least the last 2 of the past 3 years without detection of *Marteilia refringens*.

OR

4. A *zone* previously declared free from *Marteilia refringens* but in which the *disease* is detected may not be declared free from *Marteilia refringens* again until the following conditions have been met:

    a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

    b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

    c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.4. of the *Aquatic Manual*, has been in place for at least the last 2 of the past 3 years without detection of *Marteilia refringens*.

Article 2.2.4.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *Marteilia refringens* following the provisions of points 1 or 2 of Articles 2.2.4.4. or 2.2.4.5. (as relevant) may maintain its status as *Marteilia refringens* free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *Marteilia refringens* following the provisions of point 3 of Articles 2.2.4.4. or 2.2.4.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as *Marteilia refringens* free provided that conditions that are conducive to clinical expression of infection with *Marteilia refringens*, as described in Chapter 2.2.4. of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of infection with *Marteilia refringens*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.2.4.7.

Importation of live aquatic animals from a country, zone or compartment declared free from *Marteilia refringens*

When importing live *aquatic animals* of species referred to in Article 2.2.4.2. from a country, *zone* or *compartment* declared free from *Marteilia refringens*, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.4.4. or 2.2.4.5. (as applicable), whether the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from *Marteilia refringens*.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.2.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.4.3.

Article 2.2.4.8.

Community comment

The Community would suggest the OIE that, in order to improve the animal health guarantees applicable to this commodities the words"appropriate period of time" are added to point 1. Point 1 would then read:

the direct delivery into and holding of the consignment in *quarantine* facilities during an appropriate period of time;

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from *Marteilia refringens*

When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.2.4.2. from a country, *zone* or *compartment* not declared free from *Marteilia refringens*, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the direct delivery into and holding of the consignment in *quarantine* facilities;

2. the continuous isolation of the imported *aquatic animals* from the local environment;

3. the treatment of all effluent and waste material from the processing in a manner that ensures inactivation of *Marteilia refringens*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.4.3.

Article 2.2.4.9

Community comment

In the ingress the wording from "should require" should be amended to read "should assess the risk and apply risk mitigation such as".

This represents a more flexible approach- while still securing an appropriate level of protection, and is preferred by the Community. If this proposal is not acceptable, the word "should", should be replaced by "may".

Importation of live aquatic animals for processing for human consumption from a country, zone or compartment not declared free from *Marteilia refringens*

When importing, for processing for human consumption, live *aquatic animals* of species referred to in Article 2.2.4.2. from a country, *zone* or *compartment* not declared free from *Marteilia refringens*, the *Competent Authority* of the *importing country* should require that:

1. the consignment be delivered directly to and held in *quarantine* facilities until processing and/or consumption; and

2. all effluent and waste material from the processing be treated in a manner that ensures inactivation of *Marteilia refringens*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.4.3.

Article 2.2.4.10.

Community comment

The recommendation in article 2.2.4.10. seems inconsistent taking into account the definition of aquatic animals products (non-viable aquatic animals and products from aquatic animals), when this article is compared with article 2.2.4.9. To request animal health certificates for non-viable molluscs or molluscs products, taking into account their intended use and the nature of the commodities (which by nature cannot be for further farming), seems non-justifiable.

The Community would suggest the OIE to merge article 2.2.4.10 with article 2.2.4.11. The new article would read:

Importation of aquatic animal products

When importing *aquatic animal products* of species referred to in Article 2.2.4.2., the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.4.3.

Importation of aquatic animal products from a country, zone or compartment declared free from *Marteilia refringens*

When importing *aquatic animal products* of species referred to in Article 2.2.4.2. from a country, *zone* or *compartment* declared free from *Marteilia refringens*, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.4.4. or 2.2.4.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Marteilia refringens*.

The *certificate* should be in accordance with the Model Certificate in Appendix X.X.X. (under study).

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.4.3.

Appendix IX (contd)

Article 2.2.4.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from *Marteilia refringens*

When importing *aquatic animal products* of species referred to in Article 2.2.4.2. from a country, *zone* or *compartment* not declared free from *Marteilia refringens*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.4.3.

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CHAPTER 2.2.5.

INFECTION WITH *MIKROCYTOS MACKINI*

Community comments

The community agrees with the proposed chapter, but would ask the OIE to consider the comments included under the specific Articles.

Article 2.2.5.1.

For the purposes of the *Aquatic Code*, infection with *Mikrocytos mackini* means *infection* only with *Mikrocytos mackini*.

Methods for surveillance, diagnosis and confirmatory identification are provided in the *Aquatic Manual* (under study).

Article 2.2.5.2.

Scope

The recommendations in this Chapter apply to: European flat oyster (*Ostrea edulis*), Olympia oyster (*O. conchaphila*), Pacific oyster (*Crassostrea gigas*) and Eastern oyster (*C. virginica*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 2.2.5.3.

Community comment

The Community agrees with point 1 of this article but would like the inclusion in point 1a) of the following commodity "biological samples preserved for diagnostic applications in such a manner as to inactivate"*Mikrocytos Mackini*"" as this wording is included in the crustacean chapters.

The Community would like to have further clarification with regard to the maintenance of "larvae" under point 1). To our best knowledge, there is no scientific evidence that probes that larvae could be considered as safe commodities for mollusc infections which can be transmitted directly (Infections with *Bonamia ostreae, B. exitiosa* and *Mikrocytos mackini.*

Some recent studies based on the use of molecular tools, revealed infection with Mikrocytos mackini in 6 month old spat (Bower et al. 2005). Thus we think that, generally, we lack such recent studies (using molecular tools) concerning young bivalves stages (including larvae) regarding their sensitivity to these listed diseases and we consider that unless we have such studies done, "larvae" need to be deleted from point 1. This request is also reinforced by the fact that larvae produced in hatchery are submitted to transfer to nurseries or the field and thus present some high risk of disease transmission.

Bower SM, Bate K, Meyer GR (2005) Susceptibility of juvenile Crassostrea gigas and resistance of Panope abrupta to Mikrocytos mackini. J Invertebr Pathol 88:95-99

The Community would propose an alternative wording to point 1c) to avoid the accidental contamination of consignments of *Panope abrupta* with animals of other non-safe species. Point 1.c) should read:

All *commodities* containing animals only from the following species, ***Panope abrupta*** including the live *aquatic animal.*

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any *Mikrocytos mackini* related conditions, regardless of the *Mikrocytos mackini* status of the *exporting country*, *zone* or *compartment*:

   a) For the species referred to in Article 2.2.5.2. for any purpose:

      i) commercially sterile canned or other heat treated products;

      ii) ~~*gametes*, *eggs* and~~ larvae.

   b) The following *commodities* destined for human consumption from the species referred to in Article 2.2.5.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:

      i) chemically preserved products (e.g. smoked, salted, pickled, marinated~~, etc.~~);

      ii) non commercially sterile products (e.g. ready prepared meals) that have been heat treated in a manner to ensure the inactivation of the parasite;

      iii) off the shell (chilled or frozen) packaged for direct retail trade.

   c) All *commodities* from *Panope abrupta*, including the live *aquatic animal*.

   For the *commodities* referred to in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of *commodities* of a species referred to in Article 2.2.5.2., other than *commodities* referred to in point 1 of Article 2.2.5.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.2.5.7. to 2.2.5.11. relevant to the *Mikrocytos mackini* status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of any other *commodity* from bivalve species not referred to in Article 2.2.5.2. ~~n~~or in point 1c) of Article 2.2.5.3., from an *exporting country*, *zone* or *compartment* not declared free of *Mikrocytos mackini*, the *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *Mikrocytos mackini*, and the potential consequences, associated with the importation of the *commodity* prior to a decision. The *exporting country* should be informed of the outcome of this assessment.

Article 2.2.5.4.

Community comment

The Community would like to have further clarification with regard to the maintenance of different biosecurity conditions timeframes in the different mollusc chapters

***Mikrocytos mackini* free country**

A country may make a *self-declaration of freedom* from *Mikrocytos mackini* if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from *Mikrocytos mackini* if all the areas covered by the shared water are declared *Mikrocytos mackini* free *zones* (see Article 2.2.5.5.).

1. A country where none of the *susceptible species* referred to in Article 2.2.5.2. is present may make a *self-declaration of freedom* from *Mikrocytos mackini* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where any *susceptible species* referred to in Article 2.2.5.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.5. of the *Aquatic Manual*, may make a *self-declaration of freedom* from *Mikrocytos mackini* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years and infection with *Mikrocytos mackini* is not known to be established in wild populations.

OR

3. A country where the last known clinical occurrence was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to clinical expression, as described in Chapter 2.2.5. of the *Aquatic Manual*, may make a *self-declaration of freedom* from *Mikrocytos mackini* when:

    a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

    b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.5. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Mikrocytos mackini*.

OR

4. A country that has made a *self-declaration of freedom* from *Mikrocytos mackini* but in which the *disease* is detected may not make a *self-declaration of freedom* from *Mikrocytos mackini* again until the following conditions have been met:

    a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

    b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

    c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.5. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Mikrocytos mackini*.

In the meantime, part of the non-affected area may be declared a free *zone* provided that it meets the conditions in point 3 of Article 2.2.5.5.

Article 2.2.5.5.

The Community would like to have further clarification with regard to the maintenance different biosecurity conditions timeframes in the different mollusc chapters

The Community raises a concern on how to deal with intermediate hosts, if any, when regaining the freedom satus in zone or compartments according to point 4.

***Mikrocytos mackini* free zone or free compartment**

A *zone* or *compartment* free from *Mikrocytos mackini* may be established within the *territory* of one or more countries of infected or unknown status for infection with *Mikrocytos mackini* and declared free by the *Competent Authority(ies)* of the country(ies) concerned, if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a *Mikrocytos mackini* free *zone* or *compartment* if the conditions outlined below apply to all areas of the *zone* or *compartment*.

1. In a country of unknown status for *Mikrocytos mackini*, a *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.2.5.2. is present may be declared free from *Mikrocytos mackini* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. In a country of unknown status for *Mikrocytos mackini*, a *zone* or *compartment* where any *susceptible species* referred to in Article 2.2.5.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.5. of the *Aquatic Manual*, may be declared free from *Mikrocytos mackini* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years and infection with *Mikrocytos mackini* is not known to be established in wild populations.

OR

3. A *zone* or *compartment* where the last known clinical occurrence was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to clinical expression, as described in Chapter 2.2.5. of the *Aquatic Manual*, may be declared free from *Mikrocytos mackini* when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.5. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Mikrocytos mackini*.

OR

4. A *zone* previously declared free from *Mikrocytos mackini* but in which the *disease* is detected may not be declared free from *Mikrocytos mackini* again until the following conditions have been met:

a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.5. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Mikrocytos mackini*.

Article 2.2.5.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *Mikrocytos mackini* following the provisions of points 1 or 2 of Articles 2.2.5.4. or 2.2.5.5. (as relevant) may maintain its status as *Mikrocytos mackini* free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *Mikrocytos mackini* following the provisions of point 3 of Articles 2.2.5.4. or 2.2.5.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as *Mikrocytos mackini* free provided that conditions that are conducive to clinical expression of infection with *Mikrocytos mackini*, as described in Chapter 2.2.5. of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of infection with *Mikrocytos mackini*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.2.5.7.

Importation of live aquatic animals from a country, zone or compartment declared free from *Mikrocytos mackini*

When importing live *aquatic animals* of species referred to in Article 2.2.5.2. from a country, *zone* or *compartment* declared free from *Mikrocytos mackini*, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.5.4. or 2.2.5.5. (as applicable), whether the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from *Mikrocytos mackini*.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.2.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.5.3.

Article 2.2.5.8

Community comment

The Community would suggest the OIE that, in order to improve the animal health guarantees applicable to this commodities the words"appropriate period of time" are added to point 1. Point 1 would then read:

the direct delivery into and holding of the consignment in *quarantine* facilities during an appropriate period of time;

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from *Mikrocytos mackini*

When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.2.5.2. from a country, *zone* or *compartment* not declared free from *Mikrocytos mackini*, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the direct delivery into and holding of the consignment in *quarantine* facilities;

2. the continuous isolation of the imported *aquatic animals* from the local environment;

3. the treatment of all effluent and waste material from the processing in a manner that ensures inactivation of *Mikrocytos mackini*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.5.3.

Article 2.2.5.9.

Community comment

In the ingress the wording from "should require" should be amended to read "should assess the risk and apply risk mitigation such as".

This represents a more flexible approach- while still securing an appropriate level of protection, and is preferred by the Community. If this proposal is not acceptable, the word "should", should be replaced by "may".

Importation of live aquatic animals for processing for human consumption from a country, zone or compartment not declared free from *Mikrocytos mackini*

When importing, for processing for human consumption, live *aquatic animals* of species referred to in Article 2.2.5.2. from a country, *zone* or *compartment* not declared free from *Mikrocytos mackini*, the *Competent Authority* of the *importing country* should require that:

1. the consignment be delivered directly to and held in *quarantine* facilities until processing and/or consumption; and

2. all effluent and waste material from the processing be treated in a manner that ensures inactivation of *Mikrocytos mackini*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.5.3.

Article 2.2.5.10.

Community comment

The recommendation in article 2.2.5.10. seems inconsistent taking into account the definition of aquatic animals products (non-viable aquatic animals and products from aquatic animals), when this article is compared with article 2.2.5.9. To request animal health certificates for non-viable molluscs or molluscs products, taking into account their intended use and the nature of the commodities (which by nature cannot be for further farming), seems non-justifiable.

The Community would suggest the OIE to merge article 2.2.5.10 with article 2.2.5.11. The new article would read:

Importation of aquatic animal products

When importing *aquatic animal products* of species referred to in Article 2.2.5.2., the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.5.3.

Importation of aquatic animal products from a country, zone or compartment declared free from *Mikrocytos mackini*

When importing *aquatic animal products* of species referred to in Article 2.2.5.2. from a country, *zone* or *compartment* declared free from *Mikrocytos mackini*, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.5.4. or 2.2.5.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Mikrocytos mackini*.

The *certificate* should be in accordance with the Model Certificate in Appendix X.X.X. (under study).

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.5.3.

Article 2.2.5.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from *Mikrocytos mackini*

When importing *aquatic animal products* of species referred to in Article 2.2.5.2. from a country, *zone* or *compartment* not declared free from *Mikrocytos mackini*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.5.3.

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— text deleted

CHAPTER 2.2.8.

INFECTION WITH *XENOHALIOTIS CALIFORNIENSIS*

Community comments

The community agrees with the proposed chapter, but would ask the OIE to consider the comments included under the specific Articles.

Article 2.2.8.1.

For the purposes of the *Aquatic Code*, infection with *Xenohaliotis californiensis* means *infection* only with *Xenohaliotis californiensis*.

Methods for surveillance, diagnosis and confirmatory identification are provided in the *Aquatic Manual*.

Article 2.2.8.2.

Community comment

A European Union Member State put forward to the OIE a report describing the detection of the agent in *Haliotis tuberculata*. The Community would ask the OIE to include under the Scope *H. tuberculata*.

Scope

The recommendations in this Chapter apply to: black abalone (*Haliotis cracherodii*), white abalone (*H. sorenseni*), red abalone (*H. rufescens*), pink abalone (*H. corrugata*), green abalone (*H. fulgens*), flat abalone (*H. wallalensis*) and Japanese abalone (*H. discus-hannai*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 2.2.8.3.

Community comment

The Community agrees with point 1 of this article but would like the inclusion in point 1a) of the following commodity "biological samples preserved for diagnostic applications in such a manner as to inactivate"*Xenohaliotis californiensis*" as this wording is included in the crustacean chapters.

The Community would like to have further clarification with regard to the maintenance of "gametes, egg and larvae" under point 1).

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any *Xenohaliotis californiensis* related conditions, regardless of the *Xenohaliotis californiensis* status of the *exporting country*, *zone* or *compartment*:

   a) For the species referred to in Article 2.2.8.2. for any purpose:

i) commercially sterile canned or other heat treated products;

ii) *gametes*, ~~*eggs*~~ and larvae;

iii) shells.

b) The following *commodities* destined for human consumption from the species referred to in Article 2.2.8.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:

i) chemically preserved products (e.g. smoked, salted, pickled, marinated~~, etc.~~);

ii) non commercially sterile products (e.g. ready prepared meals) that have been heat treated in a manner to ensure the inactivation of the bacterium ~~parasite~~;

iii) off the shell, eviscerated abalone (chilled or frozen) packaged for direct retail trade.

For the *commodities* referred to in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of *commodities* of a species referred to in Article 2.2.8.2., other than *commodities* referred to in point 1 of Article 2.2.8.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.2.8.7. to 2.2.8.11. relevant to the *Xenohaliotis californiensis* status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of any other *commodity* from mollusc species not referred to in Article 2.2.8.2. (especially those of the genus *Haliotis*) from an *exporting country*, *zone* or *compartment* not declared free of *Xenohaliotis californiensis*, the *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *Xenohaliotis californiensis*, and the potential consequences, associated with the importation of the *commodity* prior to a decision. The *exporting country* should be informed of the outcome of this assessment.

Article 2.2.8.4.

Community comment

The Community would like to have further clarification with regard to the maintenance of different biosecurity conditions timeframes in the different mollusc chapters

***Xenohaliotis californiensis* free country**

A country may make a *self-declaration of freedom* from *Xenohaliotis californiensis* if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from *Xenohaliotis californiensis* if all the areas covered by the shared water are declared *Xenohaliotis californiensis* free *zones* (see Article 2.2.8.5.).

1. A country where none of the *susceptible species* referred to in Article 2.2.8.2. is present may make a *self-declaration of freedom* from *Xenohaliotis californiensis* when *basic biosecurity conditions* have been met continuously in the country for at least the past 3 ~~2~~ years.

OR

2. A country where any *susceptible species* referred to in Article 2.2.8.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.8. of the *Aquatic Manual*, may make a *self-declaration of freedom* from *Xenohaliotis californiensis* when *basic biosecurity conditions* have been met continuously in the country for at least the past 3 ~~2~~ years and infection with *Xenohaliotis californiensis* is not known to be established in wild populations.

OR

3. A country where the last known clinical occurrence was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to clinical expression, as described in Chapter 2.2.8. of the *Aquatic Manual*, may make a *self-declaration of freedom* from *Xenohaliotis californiensis* when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 3 ~~2~~ years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.8. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Xenohaliotis californiensis*.

OR

4. A country that has made a *self-declaration of freedom* from *Xenohaliotis californiensis* but in which the *disease* is detected may not make a *self-declaration of freedom* from *Xenohaliotis californiensis* again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.8. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Xenohaliotis californiensis*.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that it meets the conditions in point 3 of Article 2.2.8.5.

Article 2.2.8.5.

The Community would like to have further clarification with regard to the maintenance different biosecurity conditions timeframes in the different mollusc chapters

The Community raises a concern on how to deal with intermediate hosts, if any, when regaining the freedom satus in zone or compartments according to point 4.

***Xenohaliotis californiensis* free zone or free compartment**

A *zone* or *compartment* free from *Xenohaliotis californiensis* may be established within the *territory* of one or more countries of infected or unknown status for infection with *Xenohaliotis californiensis* and declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a *Xenohaliotis californiensis* free *zone* or *compartment* if the conditions outlined below apply to all areas of the *zone* or *compartment*.

1. In a country of unknown status for *Xenohaliotis californiensis*, a *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.2.8.2. is present may be declared free from *Xenohaliotis californiensis* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 3 ~~2~~ years.

OR

2. In a country of unknown status for *Xenohaliotis californiensis*, a *zone* or *compartment* where any *susceptible species* referred to in Article 2.2.8.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.8. of the *Aquatic Manual*, may be declared free from *Xenohaliotis californiensis* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 3 ~~2~~ years and infection with *Xenohaliotis californiensis* is not known to be established in wild populations.

OR

3. A *zone* or *compartment* where the last known clinical occurrence was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to clinical expression, as described in Chapter 2.2.8. of the *Aquatic Manual*, may be declared free from *Xenohaliotis californiensis* when:

    a) *basic biosecurity conditions* have been met continuously for at least the past 3 ~~2~~ years; and

    b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.8. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Xenohaliotis californiensis*.

OR

4. A *zone* previously declared free from *Xenohaliotis californiensis* but in which the *disease* is detected may not be declared free from *Xenohaliotis californiensis* again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.8. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Xenohaliotis californiensis*.

Article 2.2.8.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *Xenohaliotis californiensis* following the provisions of points 1 or 2 of Articles 2.2.8.4. or 2.2.8.5. (as relevant) may maintain its status as *Xenohaliotis californiensis* free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *Xenohaliotis californiensis* following the provisions of point 3 of Articles 2.2.8.4. or 2.2.8.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as *Xenohaliotis californiensis* free provided that conditions that are conducive to clinical expression of infection with *Xenohaliotis californiensis*, as described in Chapter 2.2.8. of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of infection with *Xenohaliotis californiensis*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.2.8.7.

Importation of live aquatic animals from a country, zone or compartment declared free from *Xenohaliotis californiensis*

When importing live *aquatic animals* of species referred to in Article 2.2.8.2. from a country, *zone* or *compartment* declared free from *Xenohaliotis californiensis*, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.8.4. or 2.2.8.5. (as applicable), whether the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from *Xenohaliotis californiensis*.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.2.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.8.3.

Article 2.2.8.8.

Community comment

The Community would suggest the OIE that, in order to improve the animal health guarantees applicable to this commodities the words"appropriate period of time" are added to point 1. Point 1 would then read:

the direct delivery into and holding of the consignment in *quarantine* facilities during an appropriate period of time;

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from *Xenohaliotis californiensis*

When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.2.8.2. from a country, *zone* or *compartment* not declared free from *Xenohaliotis californiensis*, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the direct delivery into and holding of the consignment in *quarantine* facilities;

2. the continuous isolation of the imported *aquatic animals* from the local environment;

3. the treatment of all effluent and waste material from the processing in a manner that ensures inactivation of *Xenohaliotis californiensis*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.8.3.

Article 2.2.8.9.

Community comment

In the ingress the wording from "should require" should be amended to read "should assess the risk and apply risk mitigation such as".

This represents a more flexible approach- while still securing an appropriate level of protection, and is preferred by the Community. If this proposal is not acceptable, the word "should", should be replaced by "may".

Importation of live aquatic animals for processing for human consumption from a country, zone or compartment not declared free from *Xenohaliotis californiensis*

When importing, for processing for human consumption, live *aquatic animals* of species referred to in Article 2.2.8.2. from a country, *zone* or *compartment* not declared free from *Xenohaliotis californiensis*, the *Competent Authority* of the *importing country* should require that:

1. the consignment be delivered directly to and held in *quarantine* facilities until processing and/or consumption; and

2. all effluent and waste material from the processing be treated in a manner that ensures inactivation of *Xenohaliotis californiensis*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.8.3.

Article 2.2.8.10

. **Community comment**

The recommendation in article 2.2.8.10. seems inconsistent taking into account the definition of aquatic animals products (non-viable aquatic animals and products from aquatic animals), when this article is compared with article 2.2.8.9. To request animal health certificates for non-viable molluscs or molluscs products, taking into account their intended use and the nature of the commodities (which by nature cannot be for further farming), seems non-justifiable.

The Community would suggest the OIE to merge article 2.2.8.10 with article 2.2.8.11. The new article would read:

Importation of aquatic animal products

When importing *aquatic animal products* of species referred to in Article 2.2.8.2., the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.8.3.

Importation of aquatic animal products from a country, zone or compartment declared free from *Xenohaliotis californiensis*

When importing *aquatic animal products* of species referred to in Article 2.2.8.2. from a country, *zone* or *compartment* declared free from *Xenohaliotis californiensis*, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.8.4. or 2.2.8.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Xenohaliotis californiensis*.

The *certificate* should be in accordance with the Model Certificate in Appendix X.X.X. (under study).

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.8.3.

Article 2.2.8.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from *Xenohaliotis californiensis*

When importing *aquatic animal products* of species referred to in Article 2.2.8.2. from a country, *zone* or *compartment* not declared free from *Xenohaliotis californiensis*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.8.3.

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CHAPTER 1.5.1.

RECOMMENDATIONS FOR TRANSPORT

Article 1.5.1.1.

Community comments

The Community agrees with the proposed chapter.

However, the Community encourages the OIE to dfrat another Article addressing the the transport of aquatic animals by sea.

General arrangements

1. These arrangements should be compulsory in all countries either by legislative or regulatory texts and methods of application should be described in a manual available to all concerned.

2. *Vehicles* (or *containers*) used for the *transport* of *aquatic animals* shall be designed, constructed and fitted in such a way as to withstand the weight of the *aquatic animals* and water and to ensure their safety and welfare during *transportation*. *Vehicles* shall be thoroughly cleansed and disinfected before use according to the guidelines given in the *Aquatic Code*.

3. *Vehicles* (or *containers*) in which *aquatic animals* are confined during *transport* by sea or by air shall be secured to maintain optimal conditions for the *aquatic animals* during *transport*, and to allow easy access by the attendant.

Article 1.5.1.2.

Community comment.

To better address the actual use of the containersthe Community would suggest an alternative wording to paragraph 1. it should read:

The construction of *containers* intended for *transportation* of *aquatic animals* shall be such that the accidental release of water, etc., is prevented during *transport*

Particular arrangements for containers

1. The construction of *containers* intended for *transportation* of *aquatic animals* shall be such that the release of water, etc., is prevented during *transport*.

2. In the case of the *transportation* of *aquatic animals*, provision shall be made to enable preliminary observation of the contents of *containers*.

3. *Containers* in transit in which there are *aquatic animal products* shall not be opened unless the *Competent Authorities* of the *transit country* consider it necessary. If this is the case, *containers* shall be subject to precautions taken to avoid any *risk* of contamination.

4. *Containers* shall be loaded only with one kind of product or, at least, with products not susceptible to contamination by one another.

5. It rests with each country to decide on the facilities it requires for the *transport* and importation of *aquatic animals* and *aquatic animal products* in *containers*.

Article 1.5.1.3.

Particular arrangements for the transport of aquatic animals by air

1. The stocking densities for the *transport* of *aquatic animals* in aircraft or *containers* should be determined by taking the following into consideration:

   a) the total cubic metres of available space for each type of *aquatic animal*;

   b) the oxygenation capacity of the equipment attached to the aircraft and *containers* while on the ground and during all stages of the flight.

   With regard to fish, molluscs and crustaceans, the space reserved for each *aquatic animal* species in the aircraft or *containers* that have been fitted for the separate *transportation* of several *aquatic animals* or for the *transportation* of groups of *aquatic animals* should comply with acceptable densities specified for the species in question.

2. The International Air Transport Association (IATA) Regulations for live animals (which are approved by the OIE) may be adopted if they do not conflict with national legislative arrangements. (Copies of these Regulations are obtainable from the International Air Transport Association, 800 Place Victoria, P.O. Box 113, Montreal, Quebec H4Z 1M1, Canada.)

Article 1.5.1.4.

Disinfection and other sanitary measures

1. *Disinfection* and all zoo-sanitary work should be carried out in order to:

   a) avoid all unjustified inconvenience and to prevent damage or injury to the health of people and *aquatic animals*;

   b) avoid damage to the structure of the *vehicle* or its appliances;

   c) prevent, as far as possible, any damage to *aquatic animal products*, fish *eggs* as well as mollusc and crustacean larvae.

2. On request, the *Competent Authority* shall issue the transporters with a certificate indicating the measures that have been applied to all *vehicles*, the parts of the *vehicle* that have been treated, the methods used and the reasons that led to the application of the measures.

   In the case of aircraft, the certificate may be replaced, on request, by an entry in the General Declaration of the aircraft.

3. Likewise, the *Competent Authority* shall issue on request:

a) a certificate showing the date of arrival and departure of the *aquatic animals*;

b) a certificate to the shipper or exporter, the consignee and transporter or their representatives, indicating the measures applied.

Article 1.5.1.5.

Transportation water

Water to be used for *transportation* of *aquatic animals* should be appropriately treated in order to minimise the risk of transferring pathogens. The specific recommendations are provided in the Chapter on "Disinfection" of the *Aquatic Code*.

Article 1.5.1.~~5~~6.

Treatment of transportation water

During *transportation* of *aquatic animals*, the transporter should not be permitted to evacuate and replace the water in the *transport* tanks except on specifically designated sites in the national *territory*. The waste and rinsing water should not be emptied into a drainage system that is directly connected to an aquatic environment where *aquatic animals* are present. The water from the tanks should therefore either be disinfected by a recognised process (for example, 50 mg iodine or chlorine/litre for one hour), or sprayed over land that does not drain into waters containing *aquatic animals*. Each country shall designate the sites in their national *territories* where these operations can be carried out.

Article 1.5.1.~~6~~7.

Discharge of infected material

The *Competent Authority* shall take all practical measures to prevent the discharge of any infective material into internal or territorial waters.

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Appendix XIII

CHAPTER 2.1.14.

GYRODACTYLOSIS
(*Gyrodactylus salaris*)

Community comments

The Community has strong reservations on the proposed chapter, and would ask the OIE to take our comments included under the specific Articles into account.

Article 2.1.14.1.

For the purposes of the *Aquatic Code*, gyrodactylosis means *infestation* with the viviparous freshwater ectoparasite *Gyrodactylus salaris* (Platyhelminthes and Monogenea).

Methods for surveillance and diagnosis are provided in the *Aquatic Manual*.

Article 2.1.14.2.

Scope

The recommendations in this Chapter apply to: Atlantic salmon (*Salmo salar*), rainbow trout (*Oncorhynchus mykiss*), Arctic char (*Salvelinus alpinus*), North American brook trout (*Salvelinus fontinalis*), grayling (*Thymallus thymallus*), North American lake trout (*Salvelinus namaycush*) and brown trout (*Salmo trutta*). The recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 2.1.14.3.

. Community comments

The Community but would ask the OIE to consider the following amendments :

-Inclusion in point 1a) of the following commodity "biological samples preserved for diagnostic applications in such a manner as to inactivate"Gyrodactylus salaris" as this wording is included in the crustacean chapters.

-The list of commodities under point 1 does not reflect the epidemiological characteristics of the disease. Being an ectoparasite the removal of skin and head would probably be an effective way to prevent the spreading of the disease. On the other hand merely evisceration as mentioned in b) iii) may not in itself be a safe prevention measure. The Community requests the OIE to redraft nr. 1, to take these considerations into account. The Community would like to submit the OIE with the following suggestion:

1. When authorising the importation or transit of the following commodities, the Competent Authorities should not require any gyrodactylosis related conditions, regardless of the gyrodactylosis status of the exporting country, zone or compartment:

a) For the species referred to in Article 2.1.14.2. for any purpose:

i) commercially sterile canned fish;

ii) leather made from fish skin;

iii) products of fish, where the head and skin has been removed.

iiii) samples preserved for diagnostic applications in such a manner as to inactivate"Gyrodactylus salaries"

b) Commodities other than those referred to in a) destined for human consumption from the species referred to in Article 2.1.14.2. which have been prepared in such a way as to minimise the likelihood of alternative uses.

c) For species other than those referred to in Article 2.1.14.2., all aquatic animal products.

For the commodities referred to in point 1b), Member Countries should consider introducing internal measures to prevent the commodity being used for any purpose other than for human consumption.

- Inclusion of the following phrase in line 2 of point 3 "but which could be reasonably expected to be a potential Gyrodactylus salaries carrier" to maintain the same wording as in the crustacean chapters. Therefore point 3 should be read as follows:

When considering the importation or transit of any live commodity of a species not referred in Article 2.1.14.2. but which could be reasonably expected to be a potential Gyrodactylus salaris carrier from an exporting country, zone or compartment not declared free of gyrodactylosis, the Competent Authorities of the importing country should conduct an analysis of the risk of introduction, establishment and spread of G. salaris, and the potential consequences, associated with the importation of the commodity prior to a decision. The exporting country should be informed of the outcome of this assessment

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any gyrodactylosis related conditions, regardless of the gyrodactylosis status of the *exporting country*, *zone* or *compartment*:

   a) For the species referred to in Article 2.1.14.2. for any purpose:

      i) commercially sterile canned fish;

      ii) leather made from fish skin.

   b) The following *commodities* destined for human consumption from the species referred to in Article 2.1.14.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:

      i) chemically preserved products (e.g. smoked, salted, pickled, marinated, etc.);

      ii) heat treated products (e.g. ready prepared meals and fish oil);

      iii) *eviscerated fish* (chilled or frozen) packaged for direct retail trade;

      iv) fillets or cutlets (chilled or frozen);

v) dried *eviscerated fish* (including air dried, flame dried and sun dried).

c) For species other than those referred to in Article 2.1.14.2., all *aquatic animal products*.

For the *commodities* referred to in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of *commodities* of a species referred to in Article 2.1.14.2., other than those referred to in point 1 of Article 2.1.14.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.1.14.7. to 2.1.14.11. relevant to the gyrodactylosis status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of any live *commodity* of a species not referred in Article 2.1.14.2. from an *exporting country*, *zone* or *compartment* not declared free of gyrodactylosis, the *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *G. salaris*, and the potential consequences, associated with the importation of the *commodity* prior to a decision. The *exporting country* should be informed of the outcome of this assessment.

Article 2.1.14.4.

Community comments

The Community would argue that option 2 is irrelevant for freedom from *G. Salaris. According to* Community experience, G. salaris free country, zone, compartment cannot be declared free without a carefully planned targeted surveillance scheme. In areas where the parasite is fully adapted to its host, no disease or symptoms will occur. In addition, strong seasonal fluctuation has been observed.This view is also acknowledged in Chapter 2.1.14 of the current (2006) Manual.

The different time periods in points 2 and 3 seems contradictory as well as the period of basic biosecurity conditions in point 2, should be 10 years as it is established in the other fish disease chapters.

Gyrodactylosis free country

A country may make a *self-declaration of freedom* from gyrodactylosis if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from gyrodactylosis if all the areas covered by the shared water are declared gyrodactylosis free countries, *zones* or *compartments* (see Article 2.1.14.5.).

1. A country where none of the *susceptible species* referred to in Article 2.1.14.2. is present may make a *self-declaration of freedom* from gyrodactylosis when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 2.1.14.2. are present but there has never been any observed occurrence of the *disease* for at least the past 15 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make

a *self-declaration of freedom* from gyrodactylosis when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 25 years or where the *infestation* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from gyrodactylosis when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of *G. salaris*.

OR

4. A country that has made a *self-declaration of freedom* from gyrodactylosis but in which the *disease* is subsequently detected may not make a *self-declaration of freedom* from gyrodactylosis again until the following conditions have been met:

a) on detection of the *disease*, the affected area was declared an infested zone and a *buffer zone* was established; and

b) infested populations have been destroyed or removed from the infested zone by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfestation* procedures (see *Aquatic Manual*) have been completed; and

c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of *G. salaris*.

In the meantime, part of the non-affected area may be declared a free *zone* provided that it meets the conditions in point 3 of Article 2.1.14.5.

Article 2.1.14.5.

Community comments.

The Community will claim that a zone or a compartment located in sea water would by nature comprise a disease free zone or compartment (see also Article 2.1.14.2, point 5, of the 2005 Code). The Community proposes to include a new point 5 reading:

"A zone or compartment supplied with sea water with a salinity of at least 25 parts per thousand and no live aquatic animals of species referred to in Article 2.1.14.2 have been introduced for the previous 14 days from a site of a lesser health status".

The Community would argue that for certain compartments, disease free status could be regained if aquatic aquatic animal population is removed and disposed off, the establishment is properly disinfected and where appropriate fallowed and restocked with aquatic animals from a certified free source. The Community asks the OIE AAC to include that option as an alternative as a possible new point . A proposal for a possible point 6 would be:

A compartment previously declared free from G. Salaris but in which the disease is detected may not be decl ared free from G. Salaris until the followings conditions have been met:

a) the requirements in point 4, or

b) if the compartment is supplied by water from a spring, borehole or other safe supply independent of the surrounding waters and is equipped with a barrier preventing migration of aquatic animals of susceptible species into the compartments or its water supply;

i) infected populations have been safely destroyed or removed from the infected compartment by means that minimise the risk of further spread of the disease, and appropriate disinfection procedure (see Aquatic Manual) have been completed and followed, when necessary by an appropriate fallowing period, and

ii) the compartment is repopulated with aquatic animals from a certified free population.

Finally, the Community would argue that option 2 is irrelevant for freedom from *G. Salaris. According to* Community experience, G. salaris free country, zone, compartment cannot be declared free without a carefully planned targetted surveillance scheme. In areas where the parasite is fully adapted to its host, no disease or symptoms will occur. In addition, strong seasonal fluctuation has been observed. This view is also acknowledged in Chapter 2.1.14 of the current (2006) Manual.

Gyrodactylosis free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from gyrodactylosis may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a gyrodactylosis free *zone* or *compartment* if all the *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.1.14.2. is present may be declared free from gyrodactylosis when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 2.1.14.2. are present but there has never been any observed occurrence of the *disease* for at least the past 25 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from gyrodactylosis when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 10 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 25 years or where the *infestation* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from gyrodactylosis when:

    a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

    b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of *G. salaris*.

OR

4. A *zone* previously declared free from gyrodactylosis but in which the *disease* is detected may not be declared free from gyrodactylosis again until the following conditions have been met:

    a) on detection of the *disease*, the affected area was declared an *infested zone* and a *buffer zone* was established; and

    b) infested populations have been destroyed or removed from the *infested zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfestation* procedures (see *Aquatic Manual*) have been completed; and

    c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of *G. salaris*.

Article 2.1.14.6.

MAINTENANCE OF FREE STATUS

A country, *zone* or *compartment* that is declared free from gyrodactylosis following the provisions of points 1 or 2 of Articles 2.1.14.4. or 2.1.14.5. (as relevant) may maintain its status as gyrodactylosis free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from gyrodactylosis following the provisions of point 3 of Articles 2.1.14.4. or 2.1.14.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as gyrodactylosis free provided that conditions that are conducive to clinical expression of gyrodactylosis, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infested countries and in all cases where conditions are not conducive to clinical expression of gyrodactylosis, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infestation*.

Article 2.1.14.7.

Importation of live aquatic animals from a country, zone or compartment declared free from gyrodactylosis

When importing live *aquatic animals* of species referred to in Article 2.1.14.2. from a country, *zone* or *compartment* declared free from gyrodactylosis, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.1.14.4. or 2.1.14.5. (as applicable), the place of production of the *commodity* is a country, *zone* or *compartment* declared free from gyrodactylosis.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.1.

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.14.3.

Article 2.1.14.8.

Community comment.

The Community is not confident that the risk mitigation measure in point 2b) helps to prevent the spread of the disease. The Community would propose to delete this option.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from gyrodactylosis

When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.1.14.2. from a country, *zone* or *compartment* not declared free from gyrodactylosis, the *Competent Authority* of the *importing country* should:

1. require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* attesting that:

   a) the *aquatic animals* have been held, immediately prior to export, in water with a salinity of at least 25 parts per thousand for a continuous period of at least 14 days; and

   b) no other live *aquatic animals* of the species referred to in Article 2.1.14.2. have been introduced during that period;

   OR

c) in the case of eyed eggs, the eggs have been disinfected;

OR

2. assess the risk and apply risk mitigation measures such as:

   a) the direct delivery into and holding of the consignment in *quarantine* facilities;

   b) the continuous isolation of the imported *aquatic animals* and their first generation progeny from the local environment;

   c) the treatment of all effluent and waste materials in a manner that ensures inactivation of *G. salaris*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.14.3.

Article 2.1.14.9.

Community comment

In the ingress the wording from "should require" should be amended to read "should assess the risk and apply risk mitigation such as".

This represents a more flexible approach- while still securing an appropriate level of protection, and is preferred by the Community. If this proposal is not acceptable, the word "should", should be replaced by "may".

Importation of live aquatic animals for processing for human consumption from a country, zone or compartment not declared free from gyrodactylosis

When importing, for processing for human consumption, live *aquatic animals* of species referred to in Article 2.1.14.2. from a country, *zone* or *compartment* not declared free from gyrodactylosis, the *Competent Authority* of the *importing country* should:

1. require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* attesting that the *aquatic animals* have been held, immediately prior to export, in water with a salinity of at least 25 parts per thousand for a continuous period of at least 14 days, and no other live fish of the species listed in Article 2.1.14.2. have been introduced during that period;

OR

2. require that the consignment be delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products referred to in point 1 of Article 2.1.14.3. or other products authorised by the *Competent Authority*, and all effluent and waste materials be treated in a manner that ensures inactivation of *G. salaris*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.14.3.

Article 2.1.14.10.

Community comment:

For the sake of simplification (and taking into account that the requirements of Articles 2.1.14.9 and 2.1.14.10 are identical), the Community would ask the OIE to consider merging these two Articles into one Article. Hence, Article 2.1.14.10 is superfluous.

If the OIE retains the Article, the comments forwarded in relation to Article 2.1.14.9 will also apply to Article 2.1.14.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from gyrodactylosis

When importing, for use in animal feed, or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 2.1.14.2. from a country, *zone* or *compartment* not declared free from gyrodactylosis, the *Competent Authority* of the *importing country* should:

1. require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* attesting that the *aquatic animals* have been held, immediately prior to export, in water with a salinity of at least 25 parts per thousand for a continuous period of at least 14 days, and no other live *aquatic animals* of the species referred to in Article 2.1.14.2. have been introduced during that period;

OR

2. require that the consignment be delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products referred to in point 1 of Article 2.1.14.3. or other products authorised by the *Competent Authority*, and all effluent and waste materials be treated in a manner that ensures inactivation of *G. salaris*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.14.3.

Article 2.1.14.11.

Community comment

The recommendation in Article 2.1.14.11 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 2.1.14.9. To request animal health certificates for fish products, taking into account their intended use and the nature of the commodities, seems non-justifiable.

The Community would suggest the OIE to merge article 2.1.14.11 with article 2.1.14.12. The new article would read:

Importation of aquatic animal products

When importing *aquatic animal products* of species referred to in Article 2.1.14.2., the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.14.3.

Importation of aquatic animal products from a country, zone or compartment declared free from gyrodactylosis

When importing *aquatic animal products* of species referred to in Article 2.1.14.2. from a country, *zone* or *compartment* declared free from gyrodactylosis, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.1.14.4. or 2.1.14.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from gyrodactylosis.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.1.

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.14.3.

Article 2.1.14.12.

Community comment

The Community would argue that this Article may be irrelevant taking into account the nature of the disease in question.

If the OIE wishes to maintain the Article, the Community would like the OIE to forward the justifications for its necessity.

Importation of aquatic animal products from a country, zone or compartment not declared free from gyrodactylosis

When importing *aquatic animal products* of species referred to in Article 2.1.14.2. from a country, *zone* or *compartment* not declared free from gyrodactylosis, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

1. In the case of dead *aquatic animals*, whether *eviscerated* or uneviscerated, such risk mitigation measures may include:

   a) the direct delivery into and holding of the consignment in biosecure facilities for processing to one of the products referred to in point 1 of Article 2.1.14.3. or other products authorised by the *Competent Authority*;

   b) the treatment of all effluent and waste materials in a manner that ensures inactivation of *G. salaris*.

OR

2. The *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued from the *Competent Authority* of the *exporting country* attesting that the product was derived from *aquatic animals* which had been held, immediately prior to processing, in water with a salinity of at least 25 parts per thousand for a continuous period of 14 days, and no other live *aquatic animals* of the species referred to in Article 2.1.14.2. have been introduced during that period.

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.14.3.

Appendix XIV

CHAPTER 2.1.17.

KOI HERPESVIRUS DISEASE

Community comments

The community agrees with the proposed chapter, but would ask the OIE to consider the comments included under the specific Articles.

Article 2.1.17.1.

For the purposes of the *Aquatic Code*, koi herpesvirus disease (KHVD) means *infection* with the viral species koi herpesvirus tentatively placed in the sub-family *Cyprinid herpesvirus* of the family Herpesviridae.

Methods for surveillance and diagnosis are provided in the *Aquatic Manual*.

Article 2.1.17.2.

SCOPE

The recommendations in this Chapter apply to: common carp (*Cyprinus carpio carpio*), ghost carp (*Cyprinus carpio goi)*, koi carp (*Cyprinus carpio koi*) and common carp hybrids (e.g. *Cyprinus carpio x Carassius auratus)*. These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 2.1.17.3.

Community comments

The Community agrees with point 1 but would ask the OIE to consider the following amendments :

-Inclusion in point 1a) of the following commodity "biological samples preserved for diagnostic applications in such a manner as to inactivate"KHV" as this wording is included in the crustacean chapters.

-Deletion of the words "packaged for retail sale" from point 1b)iii), as by evisceration most of the risk also associated with further processing is mitigated. If the words are not deleted, the Community asks the OIE AAC to justify its opinion that diseases have spread with eviscerated fish through further processing. To the knowledge of the Community, such spreading has not yet been recorded.

-Inclusion of the following phrase in line 2 of point 3 "but which could be reasonably expected to be a potential KHV carrier" to maintain the same wording as in the crustacean chapters. Therefore point 3 should be read as follows:

When considering the importation or transit of any live commodity of a species not referred in Article 2.1.17.2. but which could be reasonably expected to be a potential Koi herpesvirus carrier from an exporting country, zone or compartment not declared free of gyrodactylosis, the Competent Authorities of the importing country should conduct an analysis of the risk of introduction, establishment and spread of KHV, and the potential

consequences, associated with the importation of the commodity prior to a decision. The exporting country should be informed of the outcome of this assessment

COMMODITIES

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any KHVD related conditions, regardless of the KHVD status of the *exporting country*, *zone* or *compartment*:

   a) For the species referred to in Article 2.1.17.2. for any purpose:

      i) commercially sterile canned fish;

      ii) leather made from fish skin.

   b) The following *commodities* destined for human consumption from the species referred to in Article 2.1.17.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:

      i) chemically preserved products (e.g. smoked, salted, pickled, marinated, etc.);

      ii) products (e.g. ready prepared meals and fish oil) that have been heat treated in a manner to ensure the inactivation of the pathogen;

      iii) *eviscerated fish* (chilled or frozen) packaged for direct retail trade;

      iv) fillets or cutlets (chilled or frozen);

      v) dried *eviscerated fish* (including air dried, flame dried and sun dried).

   For the *commodities* referred to in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 2.1.17.2., other than those referred to in point 1 of Article 2.1.17.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.1.17.7. to 2.1.17.12. relevant to the KHVD status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of any live *commodity* of a species not referred to in Article 2.1.17.2. from an *exporting country*, *zone* or *compartment* not declared free of KHVD, the *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of KHVD, and the potential consequences, associated with the importation of the *commodity* prior to a decision. The *exporting country* should be informed of the outcome of this assessment.

Article 2.1.17.4.

KOI HERPESVIRUS DISEASE FREE COUNTRY

Community comments

The Community asks the OIE to align the 25 years period needed to obtain the freedon status for historical reasons with the 10 years period for the same purposes proposed in the mollusc and crustacean chapters. The Community proposes 10 years in all chapters.

A country may make a *self-declaration of freedom* from KHVD if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from KHVD if all the areas covered by the shared water are declared KHVD free countries or *zones* (see Article 2.1.17.5.).

1. A country where none of the *susceptible species* referred to in Article 2.1.17.2. is present may make a *self-declaration of freedom* from KHVD when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 2.1.17.2. are present but there has never been any observed occurrence of the *disease* for at least the past 25 years despite conditions that are conducive to its clinical expression, as described in Chapter 2.1.17. of the *Aquatic Manual*, may make a *self-declaration of freedom* from KHVD when *basic biosecurity conditions* have been met continuously in the country for at least the past 10 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 25 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter 2.1.17. of the *Aquatic Manual*, may make a *self-declaration of freedom* from KHVD when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.1.17. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of KHV.

OR

4. A country that has made a self-declaration of freedom from KHVD but in which the disease is subsequently detected may not make a self-declaration of freedom from KHVD again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.1.17. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of KHV.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that it meets the conditions in point 3 of Article 2.1.17.5.

Article 2.1.17.5.

KOI HERPESVIRUS DISEASE FREE ZONE OR FREE COMPARTMENT

Community comments.

The Community asks the OIE to align the 25 years period needed to obtain the freedon status for historical reasons with the 10 years period for the same purposes proposed in the mollusc and crustacean chapters. The Community proposes 10 years in all chapters.

The Community would argue that for certain compartments, disease free status could be regained if aquatic aquatic animal population is removed and disposed off, the establishment is properly disinfected and where appropriate fallowed and restocked with aquatic animals from a certified free source. The Community asks the OIE AAC to include that option as an alternative as a possible point 5. A proposal for a possible point 5 would be:

A compartment previously declared free from KHVD but in which the disease is detected may not be decl ared free from KHVD until the followings conditions have been met:

a) the requirements in point 4, or

b) if the compartment is supplied by water from a spring, borehole or other safe supply independent of the surrounding waters and is equipped with a barrier preventing migration of aquatic animals of susceptible species into the compartments or its water supply;

i) infected populations have been safely destroyed or removed from the infected compartment by means that minimise the risk of further spread of the disease, and appropriate disinfection procedure (see Aquatic Manual) have been completed and followed, when necessary by an appropriate fallowing period, and

ii) the compartment is repopulated with aquatic animals from a certified free population.

A *zone* or *compartment* within the *territory* of one or more countries not declared free from KHVD may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a KHVD free *zone* or *compartment* if all the *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.1.17.2. is present may be declared free from KHVD when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 2.1.17.2. are present but there has never been any observed occurrence of the *disease* for at least the past 25 years despite conditions that are conducive to its clinical expression, as described in Chapter 2.1.17. of the *Aquatic Manual*, may be declared free from KHVD when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 10 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 25 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter 2.1.17. of the *Aquatic Manual*, may be declared free from KHVD when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.1.17. of the *Aquatic Manual*, has been in place for at least the last 2 years without koi herpesvirus detection.

OR

4. A *zone* previously declared free from KHVD but in which the *disease* is detected may not be declared free from KHVD again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.1.17. of the *Aquatic Manual*, has been in place for at least the last 2 years without koi herpesvirus detection.

Article 2.1.17.6.

MAINTENANCE OF FREE STATUS

A country, *zone* or *compartment* that is declared free from KHVD following the provisions of points 1 or 2 of Articles 2.1.17.4. or 2.1.17.5. (as relevant) may maintain its status as KHVD free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from KHVD following the provisions of point 3 of Articles 2.1.17.4. or 2.1.17.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as KHVD free provided that conditions that are conducive to clinical expression of KHVD, as described in Chapter 2.1.17. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of KHVD, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.1.17.7.

Importation of live aquatic animals from a country, zone or compartment declared free from koi herpesvirus disease

When importing live *aquatic animals* of species referred to in Article 2.1.17.2. from a country, *zone* or *compartment* declared free from KHVD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.1.17.4. or 2.1.17.5. (as applicable), the place of production of the *commodity* is a country, *zone* or *compartment* declared free from KHVD.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.1.

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.17.3.

Article 2.1.17.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from koi herpesvirus disease

When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.1.17.2. from a country, *zone* or *compartment* not declared free from KHVD, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the direct delivery into and holding of the consignment in *quarantine* facilities;

2. the continuous isolation of the imported *aquatic animals* and their first generation progeny from the local environment;

3. the treatment of all effluent and waste materials in a manner that ensures inactivation of koi herpesvirus.

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.17.3.

Article 2.1.17.9.

Community comment

In the ingress the wording from "should require" should be amended to read "should assess the risk and apply risk mitigation such as".

This represents a more flexible approach- while still securing an appropriate level of protection, and is preferred by the Community. If this proposal is not acceptable, the word "should", should be replaced by "may".

Importation of live aquatic animals for processing for human consumption from a country, zone or compartment not declared free from koi herpesvirus disease

When importing, for processing for human consumption, live *aquatic animals* of species referred to in Article 2.1.17.2. from a country, *zone* or *compartment* not declared free from KHVD, the *Competent Authority* of the *importing country* should require that:

1. the consignment be delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products referred to in point 1 of Article 2.1.17.3. or other products authorised by the *Competent Authority*; and
2. all effluent and waste materials from the processing be treated in a manner that ensures inactivation of koi herpesvirus.

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.17.3.

Article 2.1.17.10.

Community comment:

For the sake of simplification (and taking into account that the requirements of Articles 2.1.14.9 and 2.1.14.10 are identical), the Community would ask the OIE to consider merging these two Articles into one Article. Hence, Article 2.1.14.10 is superfluous.

If the OIE retains the Article, the comments forwarded in relation to Article 2.1.14.9 will also apply to Article 2.1.14.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from koi herpesvirus disease

When importing, for use in animal feed, or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 2.1.17.2. from a country, *zone* or *compartment* not declared free from KHVD, the *Competent Authority* of the *importing country* should require that:

1. the consignment be delivered directly to and held in *quarantine* facilities for slaughter and processing to products authorised by the *Competent Authority*; and

2. all effluent and waste materials from the processing be treated in a manner that ensures inactivation of koi herpesvirus.

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.17.3.

Article 2.1.17.11.

Community comment

The recommendation in Article 2.1.17.11 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 2.1.117.9. To request animal health certificates for fish products, taking into account their intended use and the nature of the commodities, seems non-justifiable.

The Community would suggest the OIE to merge article 2.1.17.11 with article 2.1.17.12. The new article would read:

Importation of aquatic animal products

When importing *aquatic animal products* of species referred to in Article 2.1.17.2., the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.17.3.

Importation of aquatic animal products from a country, zone or compartment declared free from koi herpesvirus disease

When importing *aquatic animal products* of species referred to in Article 2.1.17.2. from a country, *zone* or *compartment* declared free from KHVD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.1.17.4. or 2.1.17.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from KHVD.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.1.

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.17.3.

Article 2.1.17.12.

Community comment

The Community would like to ask the OIE AAC to justify the need for effluent treatment in case of further poccesing of fish that has been eviscerated before entering the importing country

The Community would ask the OIE to forward any supporting evidence which justifies such risk mitigation.

The Community proposes to delete the words "whether eviscerated or" from the second paragraph.

Importation of aquatic animal products from a country, zone or compartment not declared free from koi herpesvirus disease

When importing *aquatic animal products* of species referred to in Article 2.1.17.2. from a country, *zone* or *compartment* not declared free from KHVD, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

In the case of dead *aquatic animals*, whether *eviscerated* or uneviscerated, such risk mitigation measures may include:

1. the direct delivery into and holding of the consignment in biosecure/*quarantine* facilities for processing to one of the products referred to in point 1 of Article 2.1.17.3. or other products authorised by the *Competent Authority*;

2. the treatment of all effluent and waste materials in a manner that ensures inactivation of koi herpesvirus.

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.17.3.

CHAPTER 4.1.1.

TAURA SYNDROME

Community comments

The community agrees with the proposed chapter, but would ask the OIE to consider the comments included under the specific Articles.

Article 4.1.1.1.

For the purposes of the *Aquatic Code*, Taura syndrome (TS) means *infection* with Taura syndrome virus (TSV). *Taura syndrome virus* is classified as a species in the family *Dicistroviridae*. Common synonyms are listed in Chapter 4.1.1. of the *Aquatic Manual*.

Methods for surveillance and diagnosis are provided in the *Aquatic Manual*.

Article 4.1.1.2.

Scope

The recommendations in this Chapter apply to: Pacific white shrimp or whiteleg shrimp (*Penaeus vannamei*), blue shrimp (*P. stylirostris*), northern white shrimp (*P. setiferus*), southern white shrimp (*P. schmitti*), greasyback prawn (*Metapenaeus ensis*) and giant tiger prawn (*P. monodon*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 4.1.1.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* of the *importing country* should not require any TS related conditions, regardless of the TS status of the *exporting country*, *zone* or *compartment*.

   a) For the species referred to in Article 4.1.1.2. for any purpose:

      i) commercially sterile canned products;

      ii) boiled products (e.g. boiled whole shrimp or tails, lobsters, crabs);

      iii) chemically extracted chitin;

      iv) crustacean meals or by-products made non-infectious by heating or drying (e.g. flame dried or sun dried);

      v) crustacean products made non-infectious through processing as dry feeds (e.g. pelleted or extruded feeds);

      vi) biological samples preserved for diagnostic applications in such a manner as to inactivate the TSV (e.g. formalin or alcohol preserved samples).

b) The following products destined for human consumption from species referred to in Article 4.1.1.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:

i) chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.);

ii) products that have been heat treated or dried (e.g. ready prepared meals) in a manner to ensure the inactivation of the pathogen.

For the *commodities* listed in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 4.1.1.2., other than those listed in point 1 of Article 4.1.1.3., the *Competent Authorities* of the *importing country* should require the conditions prescribed in Articles 4.1.1.7. to 4.1.1.11. relevant to the TS status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of any ~~other~~ *commodity* of a species not referred to in Article 4.1.1.2. but which could reasonably be expected to be a potential TSV carrier from an *exporting country*, *zone* or *compartment* not declared free of TS, the *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of TSV, and the potential consequences, associated with the importation of the *commodity* prior to a decision. The *exporting country* should be informed of the outcome of this assessment.

Article 4.1.1.4.

Taura syndrome free country

A country may make a *self-declaration of freedom* from TS if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from TS if all the areas covered by the shared water are declared TS free countries or *zones* (see Article 4.1.1.5.).

1. A country where none of the *susceptible species* referred to in Article 4.1.1.2. is present may make a *self-declaration of freedom* from TS when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 4.1.1.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from TS when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from TS when:

a) *basic biosecurity* conditions have been met continuously for at least the past 2 years; and

b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of TSV.

OR

4. A country that has previously made a *self-declaration of freedom* from TS but in which the *disease* is subsequently detected may not make a *self-declaration of freedom* from TS again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of TSV.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that they meet the conditions in point 3 of Article 4.1.1.5.

Article 4.1.1.5.

The Community would argue that for certain compartments, disease free status could be regained if aquatic aquatic animal population is removed and disposed off, the establishment is properly disinfected and where appropriate fallowed and restocked with aquatic animals from a certified free source. The Community asks the OIE AAC to include that option as an alternative as a possible point 5. A proposal for a possible point 5 would be:

A compartment previously declared free from TS but in which the disease is detected may not be decl ared free from TS until the followings conditions have been met:

a) the requirements in point 4, or

b) if the compartment is supplied by water from a spring, borehole or other safe supply independent of the surrounding waters and is equipped with a barrier preventing migration of aquatic animals of susceptible species into the compartments or its water supply;

i) infected populations have been safely destroyed or removed from the infected compartment by means that minimise the risk of further spread of the disease, and appropriate disinfection procedure (see Aquatic Manual) have been completed and followed, when necessary by an appropriate fallowing period, and

ii) the compartment is repopulated with aquatic animals from a certified free population.

Taura syndrome free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from TS may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a TS free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 4.1.1.2. is present may be declared free from TS when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 4.1.1.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from TS when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from TS when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 2 years without detection of TSV.

OR

4. A *zone* previously declared free from TS but in which the *disease* is detected may not be declared free from TS again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of TSV.

Article 4.1.1.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from TS following the provisions of points 1 or 2 of Articles 4.1.1.4. or 4.1.1.5. (as relevant) may maintain its status as TS free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from TS following the provisions of point 3 of Articles 4.1.1.4. or 4.1.1.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as TS free provided that conditions that are conducive to clinical expression of TS, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of TS, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 4.1.1.7.

Importation of live aquatic animals from a country, zone or compartment declared free from Taura syndrome

When importing live *aquatic animals* of species referred to in Article 4.1.1.2. from a country, *zone* or *compartment* declared free from TS, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 4.1.1.4. or 4.1.1.5. (as applicable), the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from TS.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.3.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.1.3

Article 4.1.1.8.

The Community would argue that point 2 and 3 of this article are beyond the scope of this part of the Code. See introductory remark.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from Taura syndrome

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 4.1.1.2. from a country, *zone* or *compartment* not declared free from TS, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

   a) the direct delivery into and holding of the consignment in *quarantine* facilities;

   b) the continuous isolation of the imported live *aquatic animals* and their first generation progeny from the local environment;

   c) the treatment of all effluent and waste materials from the processing in a manner that ensures inactivation of TSV.

2. If the intention of the introduction is the establishment of new genetic lines, international standards, such as the Guidelines of the International Council for the Exploration of the Seas (ICES), should be followed.

3. For the purposes of the *Aquatic Code*, the ICES Guidelines may be summarised to the following main points:

   a) identify stock of interest (cultured or wild) in its current location;

   b) evaluate stock's health/*disease* history;

   c) take and test samples for TSV, pests and general health/*disease* status;

d) import and quarantine in a secure facility a founder (F-0) population;

e) produce F-1 generation from the F-0 stock in *quarantine*;

f) culture F-1 stock and at critical times in its development (life cycle) sample and test for TSV and perform general examinations for pests and general health/*disease* status;

g) if TSV is not detected, pests are not present, and the general health/*disease* status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as TS free or specific pathogen free (SPF) for TSV;

h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.1.3.

Article 4.1.1.9.

Importation of live aquatic animals for human consumption from a country, zone or compartment not declared free from Taura syndrome

When importing, for human consumption, live *aquatic animals* of species referred to in Article 4.1.1.2. from a country, *zone* or *compartment* not declared free from TS, the *Competent Authority* of the *importing country* should require that:

1. the consignment be delivered directly to and held in isolation until consumption; and
2. all effluent, dead *aquatic animals* and waste materials from the processing be treated in a manner that ensures inactivation of TSV.

Member Countries should consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.1.3.

Article 4.1.1.10.

Community comment

The recommendation in Article 4.1.1.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 4.1.1.9. To request animal health certificates for crustacean products, taking into account their intended use and the nature of the commodities, seems non-justifiable

The Community would suggest the OIE to merge article 4.1.1.10 with article 4.1.1.11. The new article would read:

Importation of aquatic animal products

When importing *aquatic animal products* of species referred to in Article 4.1.1.2., the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 4.1.1.3.

Importation of aquatic animal products from a country, zone or compartment declared free from Taura syndrome

When importing *aquatic animal products* of species referred to in Article 4.1.1.2. from a country, *zone* or *compartment* declared free from TS, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 4.1.1.4. or 4.1.1.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from TS.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.2.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.1.3.

Appendix XV (contd)

Article 4.1.1.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from Taura syndrome

When importing *aquatic animal products* of species referred to in Article 4.1.1.2. from a country, *zone* or *compartment* not declared free from TS, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.1.3.

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CHAPTER 4.1.2.

WHITE SPOT DISEASE

Community comments

The community agrees with the proposed chapter, but would ask the OIE to consider the comments included under the specific Articles.

Article 4.1.2.1.

For the purposes of the *Aquatic Code*, white spot disease (WSD) means *infection* with white spot syndrome virus (WSSV). *White spot syndrome virus 1* is classified as a species in the genus *Whispovirus* of the family *Nimaviridae*. Common synonyms are listed in Chapter 4.1.2. of the *Aquatic Manual*.

Methods for surveillance and diagnosis are provided in the *Aquatic Manual*.

Article 4.1.2.2.

Scope

The recommendations in this Chapter apply to all decapod (order *Decapoda*) crustaceans from marine, brackish and freshwater sources. These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 4.1.2.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* of the *importing country* should not require any WSD related conditions, regardless of the WSD status of the *exporting country*, *zone* or *compartment*.

   a) For the species referred to in Article 4.1.2.2. for any purpose:

      i) commercially sterile canned products;

      ii) boiled products (e.g. boiled whole shrimp or tails, lobsters, crabs);

      iii) chemically extracted chitin;

      iv) crustacean meals or by-products made non-infectious by heating or drying (e.g. flame dried or sun dried);

      v) crustacean products made non-infectious through processing as dry feeds (e.g. pelleted or extruded feeds);

      vi) biological samples preserved for diagnostic applications in such a manner as to inactivate the WSSV (e.g. formalin or alcohol preserved samples).

   b) The following products destined for human consumption from species referred to in Article 4.1.2.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:

i) chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.)~~;~~

~~ii) products that have been heat treated or dried (e.g. ready prepared meals) in a manner to ensure the inactivation of the pathogen~~.

For the *commodities* listed in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 4.1.2.2., other than those listed in point 1 of Article 4.1.2.3., the *Competent Authorities* of the *importing country* should require the conditions prescribed in Articles 4.1.2.7. to 4.1.2.11. relevant to the WSD status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of any ~~other~~ *commodity* of a species not referred to in Article 4.1.2.2. but which could reasonably be expected to be a potential WSSV carrier from an *exporting country*, *zone* or *compartment* not declared free of WSD, the *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of WSSV, and the potential consequences, associated with the importation of the *commodity* prior to a decision. The *exporting country* should be informed of the outcome of this assessment.

Article 4.1.2.4.

White spot disease free country

A country may make a *self-declaration of freedom* from WSD if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from WSD if all the areas covered by the shared water are declared WSD free countries or *zones* (see Article 4.1.2.5.).

1. A country where none of the *susceptible species* referred to in Article 4.1.2.2. is present may make a *self-declaration of freedom* from WSD when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 4.1.2.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from WSD when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from WSD when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of WSSV.

OR

4. A country that has previously made a *self-declaration of freedom* from WSD but in which the *disease* is subsequently detected may not make a *self-declaration of freedom* from WSD again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of WSSV.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that they meet the conditions in point 3 of Article 4.1.2.5.

Article 4.1.2.5.

The Community would argue that for certain compartments, disease free status could be regained if aquatic aquatic animal population is removed and disposed off, the establishment is properly disinfected and where appropriate fallowed and restocked with aquatic animals from a certified free source. The Community asks the OIE AAC to include that option as an alternative as a possible point 5. A proposal for a possible point 5 would be:

A compartment previously declared free from WSD but in which the disease is detected may not be decl ared free from WSD until the followings conditions have been met:

a) the requirements in point 4, or

b) if the compartment is supplied by water from a spring, borehole or other safe supply independent of the surrounding waters and is equipped with a barrier preventing migration of aquatic animals of susceptible species into the compartments or its water supply;

i) infected populations have been safely destroyed or removed from the infected compartment by means that minimise the risk of further spread of the disease, and appropriate disinfection procedures (see Aquatic Manual) have been completed and followed, when necessary by an appropriate fallowing period, and

ii) the compartment is repopulated with aquatic animals from a certified free population.

White spot disease free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from WSD may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a WSD free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 4.1.2.2. is present may be declared free from WSD when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 4.1.2.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from WSD when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from WSD when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 2 years without detection of WSSV.

OR

4. A *zone* previously declared free from WSD but in which the *disease* is detected may not be declared free from WSD again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of WSSV.

Article 4.1.2.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from WSD following the provisions of points 1 or 2 of Articles 4.1.2.4. or 4.1.2.5. (as relevant) may maintain its status as WSD free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from WSD following the provisions of point 3 of Articles 4.1.2.4. or 4.1.2.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as WSD free provided that conditions that are conducive to clinical expression of WSD, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of WSD, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 4.1.2.7.

Importation of live aquatic animals from a country, zone or compartment declared free from white spot disease

When importing live *aquatic animals* of species referred to in Article 4.1.2.2. from a country, *zone* or *compartment* declared free from WSD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 4.1.2.4. or 4.1.2.5. (as applicable), the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from WSD.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.3.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.2.3.

Article 4.1.2.8.

The Community would argue that point 2 and 3 of this article are beyond the scope of this part of the Code. See introductory remark.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from white spot disease

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 4.1.2.2. from a country, *zone* or *compartment* not declared free from WSD, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

   a) the direct delivery into and holding of the consignment in *quarantine* facilities;

   b) the continuous isolation of the imported live *aquatic animals* and their first generation progeny from the local environment;

   c) the treatment of all effluent and waste materials from the processing in a manner that ensures inactivation of WSSV.

2. If the intention of the introduction is the establishment of new genetic lines, international standards, such as the Guidelines of the International Council for the Exploration of the Seas (ICES), should be followed.

3. For the purposes of the *Aquatic Code*, the ICES Guidelines may be summarised to the following main points:

   a) identify stock of interest (cultured or wild) in its current location;

   b) evaluate stock's health/*disease* history;

   c) take and test samples for WSSV, pests and general health/*disease* status;

   d) import and quarantine in a secure facility a founder (F-0) population;

   e) produce F-1 generation from the F-0 stock in *quarantine*;

   f) culture F-1 stock and at critical times in its development (life cycle) sample and test for WSSV and perform general examinations for pests and general health/*disease* status;

   g) if WSSV is not detected, pests are not present, and the general health/*disease* status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the

F-1 stock may be defined as WSD free or specific pathogen free (SPF) for WSSV;

h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.2.3.

Article 4.1.2.9.

Importation of live aquatic animals for human consumption from a country, zone or compartment not declared free from white spot disease

When importing, for human consumption, live *aquatic animals* of species referred to in Article 4.1.2.2. from a country, *zone* or *compartment* not declared free from WSD, the *Competent Authority* of the *importing country* should require that:

1. the consignment be delivered directly to and held in isolation until consumption; and
2. all effluent, dead *aquatic animals* and waste materials from the processing be treated in a manner that ensures inactivation of WSSV.

Member Countries should consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.2.3.

Article 4.1.2.10.

Community comment

The recommendation in Article 4.1.2.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 4.1.2.9. To request animal health certificates for crustacean products, taking into account their intended use and the nature of the commodities, seems non-justifiable

The Community would suggest the OIE to merge article 4.1.2.10 with article 4.1.2.11. The new article would read:

Importation of aquatic animal products

When importing *aquatic animal products* of species referred to in Article 4.1.2.2., the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 4.1.2.3.

Importation of aquatic animal products from a country, zone or compartment declared free from white spot disease

When importing *aquatic animal products* of species referred to in Article 4.1.2.2. from a country, *zone* or *compartment* declared free from WSD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 4.1.2.4. or 4.1.2.5. (as applicable), the place of production of the consignment is a country, *zone* or

compartment declared free from WSD.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.2.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.2.3.

Article 4.1.2.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from white spot disease

When importing *aquatic animal products* of species referred to in Article 4.1.2.2. from a country, *zone* or *compartment* not declared free from WSD, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.2.3.

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CHAPTER 4.1.3.

YELLOWHEAD DISEASE

Community comments

The community agrees with the proposed chapter, but would ask the OIE to consider the comments included under the specific Articles.

Article 4.1.3.1.

For the purposes of the *Aquatic Code*, yellowhead disease (YHD) means *infection* with yellow head virus (YHV). YHV and the related *Gill-associated virus* are classified as a species in the genus *Okavirus*, family *Roniviridae*, order *Nidovirales*. Common synonyms are listed in Chapter 4.1.3. of the *Aquatic Manual*.

Methods for surveillance and diagnosis are provided in the *Aquatic Manual*.

Article 4.1.3.2.

Scope

The recommendations in this Chapter apply to: giant tiger prawn (*Penaeus monodon*), brown tiger prawn (*P. esculentus*) and Kuruma prawn (*P. japonicus*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 4.1.3.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* of the *importing country* should not require any YHD related conditions, regardless of the YHD status of the *exporting country*, *zone* or *compartment*.

   a) For the species referred to in Article 4.1.3.2. for any purpose:

      i) commercially sterile canned products;

      ii) boiled products (e.g. boiled whole shrimp or tails, lobsters, crabs);

      iii) chemically extracted chitin;

      iv) crustacean meals or by-products made non-infectious by heating or drying (e.g. flame dried or sun dried);

      v) crustacean products made non-infectious through processing as dry feeds (e.g. pelleted or extruded feeds);

      vi) biological samples preserved for diagnostic applications in such a manner as to inactivate the YHV (e.g. formalin or alcohol preserved samples).

b) The following products destined for human consumption from species referred to in Article 4.1.3.2 which have been prepared in such a way as to minimise the likelihood of alternative uses:

i) chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.);

ii) products that have been heat treated or dried (e.g. ready prepared meals) in a manner to ensure the inactivation of the pathogen.

For the *commodities* listed in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 4.1.3.2., other than those listed in point 1 of Article 4.1.3.3., the *Competent Authorities* of the *importing country* should require the conditions prescribed in Articles 4.1.3.7. to 4.1.3.11. relevant to the YHD status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of any ~~other~~ *commodity* of a species not referred to in Article 4.1.3.2. but which could reasonably be expected to be a potential YHV carrier from an *exporting country*, *zone* or *compartment* not declared free of YHD, the *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of YHV, and the potential consequences, associated with the importation of the *commodity* prior to a decision. The *exporting country* should be informed of the outcome of this assessment.

Article 4.1.3.4.

Yellowhead disease free country

A country may make a *self-declaration of freedom* from YHD if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from YHD if all the areas covered by the shared water are declared YHD free countries or *zones* (see Article 4.1.3.5.).

1. A country where none of the *susceptible species* referred to in Article 4.1.3.2. is present may make a *self-declaration of freedom* from YHD when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 4.1.3.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from YHD when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from YHD when:

a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of YHV.

OR

4. A country that has previously made a *self-declaration of freedom* from YHD but in which the *disease* is subsequently detected may not make a *self-declaration of freedom* from YHD again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of YHV.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that they meet the conditions in point 3 of Article 4.1.3.5.

Article 4.1.3.5.

The Community would argue that for certain compartments, disease free status could be regained if aquatic aquatic animal population is removed and disposed off, the establishment is properly disinfected and where appropriate fallowed and restocked with aquatic animals from a certified free source. The Community asks the OIE AAC to include that option as an alternative as a possible point 5. A proposal for a possible point 5 would be:

A compartment previously declared free from YHD but in which the disease is detected may not be decl ared free from YHD until the followings conditions have been met:

a) the requirements in point 4, or

b) if the compartment is supplied by water from a spring, borehole or other safe supply independent of the surrounding waters and is equipped with a barrier preventing migration of aquatic animals of susceptible species into the compartments or its water supply;

i) infected populations have been safely destroyed or removed from the infected compartment by means that minimise the risk of further spread of the disease, and appropriate disinfection procedures (see Aquatic Manual) have been completed and followed, when necessary by an appropriate fallowing period, and

ii) the compartment is repopulated with aquatic animals from a certified free population.

Yellowhead disease free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from YHD may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a YHD free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 4.1.3.2. is present may be declared free from YHD when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 4.1.3.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from YHD when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from YHD when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 2 years without detection of YHV.

OR

4. A *zone* previously declared free from YHD but in which the *disease* is detected may not be declared free from YHD again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of YHV.

Article 4.1.3.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from YHD following the provisions of points 1 or 2 of Articles 4.1.3.4. or 4.1.3.5. (as relevant) may maintain its status as YHD free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from YHD following the provisions of point 3 of Articles 4.1.3.4. or 4.1.3.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as YHD free provided that conditions that are conducive to clinical expression of YHD, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of YHD, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 4.1.3.7.

Importation of live aquatic animals from a country, zone or compartment declared free from yellowhead disease

When importing live *aquatic animals* of species referred to in Article 4.1.3.2. from a country, *zone* or *compartment* declared free from YHD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 4.1.3.4. or 4.1.3.5. (as applicable), the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from YHD.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.3.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.3.3.

Article 4.1.3.8.

The Community would argue that point 2 and 3 of this article are beyond the scope of this part of the Code. See introductory remark.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from yellowhead disease

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 4.1.3.2. from a country, *zone* or *compartment* not declared free from YHD, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:
   a) the direct delivery into and holding of the consignment in *quarantine* facilities;
   b) the continuous isolation of the imported live *aquatic animals* and their first generation progeny from the local environment;
   c) the treatment of all effluent and waste materials from the processing in a manner that ensures inactivation of YHV.
2. If the intention of the introduction is the establishment of new genetic lines, international standards, such as the Guidelines of the International Council for the Exploration of the Seas (ICES), should be followed.
3. For the purposes of the *Aquatic Code*, the ICES Guidelines may be summarised to the following main points:
   a) identify stock of interest (cultured or wild) in its current location;
   b) evaluate stock's health/*disease* history;
   c) take and test samples for YHV, pests and general health/*disease* status;
   d) import and quarantine in a secure facility a founder (F-0) population;
   e) produce F-1 generation from the F-0 stock in *quarantine*;
   f) culture F-1 stock and at critical times in its development (life cycle) sample and test for YHV and perform general examinations for pests and general health/*disease* status;
   g) if YHV is not detected, pests are not present, and the general health/*disease* status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as YHD free or specific pathogen free (SPF) for YHV;

h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.3.3.

Article 4.1.3.9.

Importation of live aquatic animals for human consumption from a country, zone or compartment not declared free from yellowhead disease

When importing, for human consumption, live *aquatic animals* of species referred to in Article 4.1.3.2. from a country, *zone* or *compartment* not declared free from YHD, the *Competent Authority* of the *importing country* should require that:

1. the consignment be delivered directly to and held in isolation until consumption; and
2. all effluent, dead *aquatic animals* and waste materials from the processing be treated in a manner that ensures inactivation of YHV.

Member Countries should consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.3.3.

Article 4.1.3.10.

Community comment

The recommendation in Article 4.1.3.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 4.1.3.9. To request animal health certificates for crustacean products, taking into account their intended use and the nature of the commodities, seems non-justifiable

The Community would suggest the OIE to merge article 4.1.3.10 with article 4.1.3.11. The new article would read:

Importation of aquatic animal products

When importing *aquatic animal products* of species referred to in Article 4.1.3.2., the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 4.1.3.3.

Importation of aquatic animal products from a country, zone or compartment declared free from yellowhead disease

When importing *aquatic animal products* of species referred to in Article 4.1.3.2. from a country, *zone* or *compartment* declared free from YHD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 4.1.3.4. or 4.1.3.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from YHD.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.2.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.3.3.

Article 4.1.3.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from yellowhead disease

When importing *aquatic animal products* of species referred to in Article 4.1.3.2. from a country, *zone* or *compartment* not declared free from YHD, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.3.3.

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CHAPTER 4.1.4.

TETRAHEDRAL BACULOVIROSIS

Community comments

The community agrees with the proposed chapter, but would ask the OIE to consider the comments included under the specific Articles.

Article 4.1.4.1.

For the purposes of the *Aquatic Code*, tetrahedral baculovirosis means *infection* with *Baculovirus penaei* (BPV). This virus is closely related to *Penaeus monodon baculovirus* (Chapter 4.1.5.) which has been classified as a tentative species in the genus *Nucleopolyhedrovirus*. Common synonyms are listed in Chapter 4.1.4. of the *Aquatic Manual*.

Methods for surveillance and diagnosis are provided in the *Aquatic Manual*.

Article 4.1.4.2.

Scope

The recommendations in this Chapter apply to the following genera: *Penaeus, Trachypenaeus* and *Protrachypene*. These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 4.1.4.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* of the *importing country* should not require any tetrahedral baculovirosis related conditions, regardless of the tetrahedral baculovirosis status of the *exporting country*, *zone* or *compartment*.

   a) For the species referred to in Article 4.1.4.2. for any purpose:

      i) commercially sterile canned products;

      ii) boiled products (e.g. boiled whole shrimp or tails, lobsters, crabs);

      iii) chemically extracted chitin;

      iv) crustacean meals or by-products made non-infectious by heating or drying (e.g. flame dried or sun dried);

      v) crustacean products made non-infectious through processing as dry feeds (e.g. pelleted or extruded feeds);

      vi) biological samples preserved for diagnostic applications in such a manner as to inactivate the BPV (e.g. formalin or alcohol preserved samples).

b) The following products destined for human consumption from species referred to in Article 4.1.4.2 which have been prepared in such a way as to minimise the likelihood of alternative uses:

i) chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.);

ii) products that have been heat treated or dried (e.g. ready prepared meals) in a manner to ensure the inactivation of the pathogen;

iii) de-headed and ~~de veined~~ "de-veined" (intestine removed) shrimp tails.

For the *commodities* listed in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 4.1.4.2., other than those listed in point 1 of Article 4.1.4.3., the *Competent Authorities* of the *importing country* should require the conditions prescribed in Articles 4.1.4.7. to 4.1.4.11., relevant to the tetrahedral baculovirosis status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of any ~~other~~ *commodity* of a species not referred to in Article 4.1.4.2. but which could reasonably be expected to be a potential BPV carrier from an *exporting country*, *zone* or *compartment* not declared free of tetrahedral baculovirosis, the *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of BPV, and the potential consequences, associated with the importation of the *commodity* prior to a decision. The *exporting country* should be informed of the outcome of this assessment.

Article 4.1.4.4.

Tetrahedral baculovirosis free country

A country may make a *self-declaration of freedom* from tetrahedral baculovirosis if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from tetrahedral baculovirosis if all the areas covered by the shared water are declared tetrahedral baculovirosis free countries or *zones* (see Article 4.1.4.5.).

1. A country where none of the *susceptible species* referred to in Article 4.1.4.2. is present may make a *self-declaration of freedom* from tetrahedral baculovirosis when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 4.1.4.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from tetrahedral baculovirosis when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from tetrahedral baculovirosis when:

a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of BPV.

OR

4. A country that has previously made a *self-declaration of freedom* from tetrahedral baculovirosis but in which the *disease* is subsequently detected may not make a *self-declaration of freedom* from tetrahedral baculovirosis again until the following conditions have been met:

a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of BPV.

In the meantime, part of the non-affected area may be declared a free *zone* provided that they meet the conditions in point 3 of Article 4.1.4.5.

Article 4.1.4.5.

Tetrahedral baculovirosis free zone or free compartment

The Community would argue that for certain compartments, disease free status could be regained if aquatic aquatic animal population is removed and disposed off, the establishment is properly disinfected and where appropriate fallowed and restocked with aquatic animals from a certified free source. The Community asks the OIE AAC to include that option as an alternative as a possible point 5. A proposal for a possible point 5 would be:

A compartment previously declared free from tetrahedral baculovirosis but in which the disease is detected may not be decl ared free from tetrahedral baculovirosis until the followings conditions have been met:

a) the requirements in point 4, or

b) if the compartment is supplied by water from a spring, borehole or other safe supply independent of the surrounding waters and is equipped with a barrier preventing migration of aquatic animals of susceptible species into the compartments or its water supply;

i) infected populations have been safely destroyed or removed from the infected compartment by means that minimise the risk of further spread of the disease, and appropriate disinfection procedures (see Aquatic Manual) have been completed and followed, when necessary by an appropriate fallowing period, and

ii) the compartment is repopulated with aquatic animals from a certified free population.

A *zone* or *compartment* within the *territory* of one or more countries not declared free from tetrahedral baculovirosis may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a tetrahedral baculovirosis free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 4.1.4.2. is present may be declared free from tetrahedral baculovirosis when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 4.1.4.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from tetrahedral baculovirosis when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from tetrahedral baculovirosis when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 2 years without detection of BPV.

OR

4. A *zone* previously declared free from tetrahedral baculovirosis but in which the *disease* is detected may not be declared free from tetrahedral baculovirosis again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of BPV.

Article 4.1.4.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from tetrahedral baculovirosis following the provisions of points 1 or 2 of Articles 4.1.4.4. or 4.1.4.5. (as relevant) may maintain its status as tetrahedral baculovirosis free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from tetrahedral baculovirosis following the provisions of point 3 of Articles 4.1.4.4. or 4.1.4.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as tetrahedral baculovirosis free provided that conditions that are conducive to clinical expression of tetrahedral baculovirosis, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of tetrahedral baculovirosis, *targeted surveillance* needs to be continued

at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 4.1.4.7.

Importation of live aquatic animals from a country, zone or compartment declared free from tetrahedral baculovirosis

When importing live *aquatic animals* of species referred to in Article 4.1.4.2. from a country, *zone* or *compartment* declared free from tetrahedral baculovirosis, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 4.1.4.4. or 4.1.4.5. (as applicable), the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from tetrahedral baculovirosis.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.3.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.4.3.

Article 4.1.4.8.

The Community would argue that point 2 and 3 of this article are beyond the scope of this part of the Code. See introductory remark.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from tetrahedral baculovirosis

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 4.1.4.2. from a country, *zone* or *compartment* not declared free from tetrahedral baculovirosis, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

   a) the direct delivery into and holding of the consignment in *quarantine* facilities;

   b) the continuous isolation of the imported live *aquatic animals* and their first generation progeny from the local environment;

   c) the treatment of all effluent and waste materials from the processing in a manner that ensures inactivation of BPV.

2. If the intention of the introduction is the establishment of new genetic lines, international standards, such as the Guidelines of the International Council for the Exploration of the Seas (ICES), should be followed.

3. For the purposes of the *Aquatic Code*, the ICES Guidelines may be summarised to the following main points:

   a) identify stock of interest (cultured or wild) in its current location;

   b) evaluate stock's health/*disease* history;

   c) take and test samples for BPV, pests and general health/*disease* status;

   d) import and quarantine in a secure facility a founder (F-0) population;

e) produce F-1 generation from the F-0 stock in *quarantine*;

f) culture F-1 stock and at critical times in its development (life cycle) sample and test for BPV and perform general examinations for pests and general health/*disease* status;

g) if BPV is not detected, pests are not present, and the general health/*disease* status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as tetrahedral baculovirosis free or specific pathogen free (SPF) for BPV;

h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.4.3.

Article 4.1.4.9.

Importation of live aquatic animals for human consumption from a country, zone or compartment not declared free from tetrahedral baculovirosis

When importing, for human consumption, live *aquatic animals* of species referred to in Article 4.1.4.2. from a country, *zone* or *compartment* not declared free from tetrahedral baculovirosis, the *Competent Authority* of the *importing country* should require that:

1. the consignment be delivered directly to and held in isolation until consumption; and
2. all effluent, dead *aquatic animals* and waste materials from the processing be treated in a manner that ensures inactivation of BPV.

Member Countries should consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.4.3.

Article 4.1.4.10.

Community comment

The recommendation in Article 4.1.4.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 4.1.4.9. To request animal health certificates for crustacean products, taking into account their intended use and the nature of the commodities, seems non-justifiable.

The Community would suggest the OIE to merge article 4.1.4.10 with article 4.1.4.11. The new article would read:

Importation of aquatic animal products

When importing *aquatic animal products* of species referred to in Article 4.1.4.2., the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 4.1.4.3.

Importation of aquatic animal products from a country, zone or compartment declared free from

tetrahedral baculovirosis

When importing *aquatic animal products* of species referred to in Article 4.1.4.2. from a country, *zone* or *compartment* declared free from tetrahedral baculovirosis, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 4.1.4.4. or 4.1.4.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from tetrahedral baculovirosis.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.2.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.4.3.

Article 4.1.4.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from tetrahedral baculovirosis

When importing *aquatic animal products* of species referred to in Article 4.1.4.2. from a country, *zone* or *compartment* not declared free from tetrahedral baculovirosis, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.4.3.

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CHAPTER 4.1.5.

SPHERICAL BACULOVIROSIS

Community comments

The community agrees with the proposed chapter, but would ask the OIE to consider the comments included under the specific Articles.

Article 4.1.5.1.

For the purposes of the *Aquatic Code*, spherical baculovirosis means *infection* with *Penaeus monodon* baculovirus (MBV). *Penaeus monodon baculovirus* is classified as a tentative species in the genus *Nucleopolyhedrovirus*. Common synonyms are listed in Chapter 4.1.5. of the *Aquatic Manual*.

Methods for surveillance and diagnosis are provided in the *Aquatic Manual*.

Article 4.1.5.2.

Scope

The recommendations in this Chapter apply to the following genera: *Penaeus* and *Metapenaeus*. These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 4.1.5.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* of the *importing country* should not require any spherical baculovirosis related conditions, regardless of the spherical baculovirosis status of the *exporting country*, *zone* or *compartment*.

   a) For the species referred to in Article 4.1.5.2. for any purpose:

      i) commercially sterile canned products;

      ii) boiled products (e.g. boiled whole shrimp or tails, lobsters, crabs);

      iii) chemically extracted chitin;

      iv) crustacean meals or by-products made non-infectious by heating or drying (e.g. flame dried or sun dried);

      v) crustacean products made non-infectious through processing as dry feeds (e.g. pelleted or extruded feeds);

      vi) biological samples preserved for diagnostic applications in such a manner as to inactivate the MBV (e.g. formalin or alcohol preserved samples).

b) The following products destined for human consumption from species referred to in Article 4.1.5.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:

i) chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.);

ii) products that have been heat treated or dried (e.g. ready prepared meals) in a manner to ensure the inactivation of the pathogen;

iii) de-headed and ~~de veined~~ "de-veined" (intestine removed) shrimp tails.

For the *commodities* listed in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 4.1.5.2., other than those listed in point 1 of Article 4.1.5.3., the *Competent Authorities* of the *importing country* should require the conditions prescribed in Articles 4.1.5.7. to 4.1.5.11. relevant to the spherical baculovirosis status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of any ~~other~~ *commodity* of a species not referred to in Article 4.1.5.2. but which could reasonably be expected to be a potential MBV carrier from an *exporting country*, *zone* or *compartment* not declared free of spherical baculovirosis, the *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of MBV, and the potential consequences, associated with the importation of the *commodity*, prior to a decision. The *exporting country* should be informed of the outcome of this assessment.

Article 4.1.5.4.

Spherical baculovirosis free country

A country may make a *self-declaration of freedom* from spherical baculovirosis if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from spherical baculovirosis if all the areas covered by the shared water are declared spherical baculovirosis free countries or *zones* (see Article 4.1.5.5.).

1. A country where none of the *susceptible species* referred to in Article 4.1.5.2. is present may make a *self-declaration of freedom* from spherical baculovirosis when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 4.1.5.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from spherical baculovirosis when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from spherical baculovirosis when:

a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of MBV.

OR

4. A country that has previously made a *self-declaration of freedom* from spherical baculovirosis but in which the *disease* is subsequently detected may not make a *self-declaration of freedom* from spherical baculovirosis again until the following conditions have been met:

a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of MBV.

In the meantime, part of the non-affected area may be declared a free *zone* provided that they meet the conditions in point 3 of Article 4.1.5.5.

Article 4.1.5.5.

Spherical baculovirosis free zone or free compartment

The Community would argue that for certain compartments, disease free status could be regained if aquatic aquatic animal population is removed and disposed off, the establishment is properly disinfected and where appropriate fallowed and restocked with aquatic animals from a certified free source. The Community asks the OIE AAC to include that option as an alternative as a possible point 5. A proposal for a possible point 5 would be:

A compartment previously declared free from spherical baculovirosis but in which the disease is detected may not be declared free from spherical baculovirosis until the followings conditions have been met:

a) the requirements in point 4, or

b) if the compartment is supplied by water from a spring, borehole or other safe supply independent of the surrounding waters and is equipped with a barrier preventing migration of aquatic animals of susceptible species into the compartments or its water supply;

i) infected populations have been safely destroyed or removed from the infected compartment by means that minimise the risk of further spread of the disease, and appropriate disinfection procedures (see Aquatic Manual) have been completed and followed, when necessary by an appropriate fallowing period, and

ii) the compartment is repopulated with aquatic animals from a certified free population.

A *zone* or *compartment* within the *territory* of one or more countries not declared free from spherical baculovirosis may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a spherical baculovirosis free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 4.1.5.2. is present may be declared free from spherical baculovirosis when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 4.1.5.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from spherical baculovirosis when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from spherical baculovirosis when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 2 years without detection of MBV.

OR

4. A *zone* previously declared free from spherical baculovirosis but in which the *disease* is detected may not be declared free from spherical baculovirosis again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of MBV.

Article 4.1.5.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from spherical baculovirosis following the provisions of points 1 or 2 of Articles 4.1.5.4. or 4.1.5.5. (as relevant) may maintain its status as spherical baculovirosis free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from spherical baculovirosis following the provisions of point 3 of Articles 4.1.5.4. or 4.1.5.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as spherical baculovirosis free provided that conditions that are conducive to clinical expression of spherical baculovirosis, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of spherical baculovirosis, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 4.1.5.7.

Importation of live aquatic animals from a country, zone or compartment declared free from spherical baculovirosis

When importing live *aquatic animals* of species referred to in Article 4.1.5.2. from a country, *zone* or *compartment* declared free from spherical baculovirosis, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 4.1.5.4. or 4.1.5.5. (as applicable), the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from spherical baculovirosis.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.3.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.5.3. Appendix XIX (contd)

Article 4.1.5.8.

The Community would argue that point 2 and 3 of this article are beyond the scope of this part of the Code. See introductory remark.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from spherical baculovirosis

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 4.1.5.2. from a country, *zone* or *compartment* not declared free from spherical baculovirosis, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

   a) the direct delivery into and holding of the consignment in *quarantine* facilities;

   b) the continuous isolation of the imported live *aquatic animals* and their first generation progeny from the local environment;

   c) the treatment of all effluent and waste materials from the processing in a manner that ensures inactivation of MBV.

2. If the intention of the introduction is the establishment of new genetic lines, international standards, such as the Guidelines of the International Council for the Exploration of the Seas (ICES), should be followed.

3. For the purposes of the *Aquatic Code*, the ICES Guidelines may be summarised to the following main points:

   a) identify stock of interest (cultured or wild) in its current location;

   b) evaluate stock's health/*disease* history;

   c) take and test samples for MBV, pests and general health/*disease* status;

   d) import and quarantine in a secure facility a founder (F-0) population;

   e) produce F-1 generation from the F-0 stock in *quarantine*;

   f) culture F-1 stock and at critical times in its development (life cycle) sample and test for MBV and perform general examinations for pests and general health/*disease* status;

   g) if MBV is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as spherical baculovirosis free or specific pathogen free (SPF) for

MBV;

h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.5.3.

Article 4.1.5.9.

Importation of live aquatic animals for human consumption from a country, zone or compartment not declared free from spherical baculovirosis

When importing, for human consumption, live *aquatic animals* of species referred to in Article 4.1.5.2. from a country, *zone* or *compartment* not declared free from spherical baculovirosis, the *Competent Authority* of the *importing country* should require that:

1. the consignment be delivered directly to and held in isolation until consumption; and

2. all effluent, dead *aquatic animals* and waste materials from the processing be treated in a manner that ensures inactivation of MBV.

Member Countries should consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.5.3.

Article 4.1.5.10.

Community comment

The recommendation in Article 4.1.5.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 4.1.5.9. To request animal health certificates for crustacean products, taking into account their intended use and the nature of the commodities, seems non-justifiable.

The Community would suggest the OIE to merge article 4.1.5.10 with article 4.1.5.11. The new article would read:

Importation of aquatic animal products

When importing *aquatic animal products* of species referred to in Article 4.1.5.2., the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 4.1.5.3.

Importation of aquatic animal products from a country, zone or compartment declared free from spherical baculovirosis

When importing *aquatic animal products* of species referred to in Article 4.1.5.2. from a country, *zone* or *compartment* declared free from spherical baculovirosis, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 4.1.5.4. or 4.1.5.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from spherical baculovirosis.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.2.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.5.3.

Article 4.1.5.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from spherical baculovirosis

When importing *aquatic animal products* of species referred to in Article 4.1.5.2. from a country, *zone* or *compartment* not declared free from spherical baculovirosis, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.5.3.

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CHAPTER 4.1.6.

INFECTIOUS HYPODERMAL AND HAEMATOPOIETIC NECROSIS

Community comments

The community agrees with the proposed chapter, but would ask the OIE to consider the comments included under the specific Articles.

Article 4.1.6.1.

For the purposes of the *Aquatic Code*, infectious hypodermal and haematopoietic necrosis (IHHN) means *infection* with infectious hypodermal and haematopoietic necrosis virus (IHHNV). IHHNV is classified as the species *Penaeus stylirostris densovirus* in the genus *Brevidensovirus* in the family *Parvoviridae*.

Methods for surveillance and diagnosis are provided in the *Aquatic Manual*.

Article 4.1.6.2.

Scope

The recommendations in this Chapter apply to: giant tiger prawn (*Penaeus monodon*), Pacific white shrimp (*P. vannamei*) and blue shrimp (*P. stylirostris*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 4.1.6.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* of the *importing country* should not require any IHHN related conditions, regardless of the IHHN status of the *exporting country*, *zone* or *compartment*.

   a) For the species referred to in Article 4.1.6.2. for any purpose:

      i) commercially sterile canned products;

      ii) boiled products (e.g. boiled whole shrimp or tails, lobsters, crabs);

      iii) chemically extracted chitin;

      iv) crustacean meals or by-products made non-infectious by heating or drying (e.g. flame dried or sun dried);

      v) crustacean products made non-infectious through processing as dry feeds (e.g. pelleted or extruded feeds);

      vi) biological samples preserved for diagnostic applications in such a manner as to inactivate the IHHNV (e.g. formalin or alcohol preserved samples).

   b) The following products destined for human consumption from species referred to in Article 4.1.6.2 which have been prepared in such a way as to minimise the likelihood of alternative uses:

i) chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.);

ii) products that have been heat treated or dried (e.g. ready prepared meals) in a manner to ensure the inactivation of the pathogen.

For the *commodities* listed in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 4.1.6.2., other than those listed in point 1 of Article 4.1.6.3., the *Competent Authorities* of the *importing country* should require the conditions prescribed in Articles 4.1.6.7. to 4.1.6.11. relevant to the IHHN status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of any ~~other~~ *commodity* of a species not referred to in Article 4.1.6.2. but which could reasonably be expected to be a potential IHHNV carrier from an *exporting country*, *zone* or *compartment* not declared free of IHHN, the *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of IHHNV, and the potential consequences, associated with the importation of the *commodity* prior to a decision. The *exporting country* should be informed of the outcome of this assessment.

Article 4.1.6.4.

Infectious hypodermal and haematopoietic necrosis free country

A country may make a *self-declaration of freedom* from IHHN if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from IHHN if all the areas covered by the shared water are declared IHHN free countries or *zones* (see Article 4.1.6.5.).

1. A country where none of the *susceptible species* referred to in Article 4.1.6.2. is present may make a *self-declaration of freedom* from IHHN when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 4.1.6.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from IHHN when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from IHHN when:

a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of IHHNV.

OR

4. A country that has previously made a *self-declaration of freedom* from IHHN but in which the *disease* is subsequently detected may not make a *self-declaration of freedom* from IHHN again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of IHHNV.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that they meet the conditions in point 3 of Article 4.1.6.5.

Article 4.1.6.5.

Infectious hypodermal and haematopoietic necrosis free zone or free compartment

The Community would argue that for certain compartments, disease free status could be regained if aquatic aquatic animal population is removed and disposed off, the establishment is properly disinfected and where appropriate fallowed and restocked with aquatic animals from a certified free source. The Community asks the OIE AAC to include that option as an alternative as a possible point 5. A proposal for a possible point 5 would be:

A compartment previously declared free from IHHN but in which the disease is detected may not be decl ared free from IHNN until the followings conditions have been met:

a) the requirements in point 4, or

b) if the compartment is supplied by water from a spring, borehole or other safe supply independent of the surrounding waters and is equipped with a barrier preventing migration of aquatic animals of susceptible species into the compartments or its water supply;

i) infected populations have been safely destroyed or removed from the infected compartment by means that minimise the risk of further spread of the disease, and appropriate disinfection procedures (see Aquatic Manual) have been completed and followed, when necessary by an appropriate fallowing period, and

ii) the compartment is repopulated with aquatic animals from a certified free population.

A *zone* or *compartment* within the *territory* of one or more countries not declared free from IHHN may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared an IHHN free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 4.1.6.2. is present may be declared free from IHHN when *basic biosecurity conditions* have been met continuously in the *zone* or

compartment for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 4.1.6.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from IHHN when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from IHHN when:

    a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

    b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 2 years without detection of IHHNV.

OR

4. A *zone* previously declared free from IHHN but in which the *disease* is detected may not be declared free from IHHN again until the following conditions have been met:

    a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

    b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

    c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of IHHNV.

Article 4.1.6.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from IHHN following the provisions of points 1 or 2 of Articles 4.1.6.4. or 4.1.6.5. (as relevant) may maintain its status as IHHN free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from IHHN following the provisions of point 3 of Articles 4.1.6.4. or 4.1.6.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as IHHN free provided that conditions that are conducive to clinical expression of IHHN, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of IHHN, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 4.1.6.7.

Importation of live aquatic animals from a country, zone or compartment declared free from infectious hypodermal and haematopoietic necrosis

When importing live *aquatic animals* of species referred to in Article 4.1.6.2. from a country, *zone* or *compartment* declared free from IHHN, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 4.1.6.4. or 4.1.6.5. (as applicable), the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from IHHN.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.3.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.6.3.

Article 4.1.6.8.

The Community would argue that point 2 and 3 of this article are beyond the scope of this part of the Code. See introductory remark.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from infectious hypodermal and haematopoietic necrosis

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 4.1.6.2. from a country, *zone* or *compartment* not declared free from IHHN, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

   a) the direct delivery into and holding of the consignment in *quarantine* facilities;

   b) the continuous isolation of the imported live *aquatic animals* and their first generation progeny from the local environment;

   c) the treatment of all effluent and waste materials from the processing in a manner that ensures inactivation of IHHNV.

2. If the intention of the introduction is the establishment of new genetic lines, international standards, such as the Guidelines of the International Council for the Exploration of the Seas (ICES), should be followed.

3. For the purposes of the *Aquatic Code*, the ICES Guidelines may be summarised to the following main points:

   a) identify stock of interest (cultured or wild) in its current location;

   b) evaluate stock's health/*disease* history;

   c) take and test samples for IHHNV, pests and general health/*disease* status;

   d) import and quarantine in a secure facility a founder (F-0) population;

   e) produce F-1 generation from the F-0 stock in *quarantine*;

   f) culture F-1 stock and at critical times in its development (life cycle) sample and test for IHHNV and perform general examinations for pests and general health/*disease* status;

   g) if IHHNV is not detected, pests are not present, and the general health/*disease* status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*,

the F-1 stock may be defined as IHHN free or specific pathogen free (SPF) for IHHNV;

h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.6.3.

Article 4.1.6.9.

Importation of live aquatic animals for human consumption from a country, zone or compartment not declared free from infectious hypodermal and haematopoietic necrosis

When importing, for human consumption, live *aquatic animals* of species referred to in Article 4.1.6.2. from a country, *zone* or *compartment* not declared free from IHHN, the *Competent Authority* of the *importing country* should require that:

1. the consignment be delivered directly to and held in isolation until consumption; and
2. all effluent, dead *aquatic animals* and waste materials from the processing be treated in a manner that ensures inactivation of IHHNV.

Member Countries should consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.6.3.

Article 4.1.6.10.

Importation of aquatic animal products from a country, zone or compartment declared free from infectious hypodermal and haematopoietic necrosis

Community comment

The recommendation in Article 4.1.6.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 4.1.16.9. To request animal health certificates for crustacean products, taking into account their intended use and the nature of the commodities, seems non-justifiable.

The Community would suggest the OIE to merge article 4.1.6.10 with article 4.1.6.11. The new article would read:

Importation of aquatic animal products

When importing *aquatic animal products* of species referred to in Article 4.1.6.2., the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 4.1.6.3.

When importing *aquatic animal products* of species referred to in Article 4.1.6.2. from a country, *zone* or *compartment* declared free from IHHN, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in

Articles 4.1.6.4. or 4.1.6.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from IHHN.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.2.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.6.3.

Article 4.1.6.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from infectious hypodermal and haematopoietic necrosis

When importing *aquatic animal products* of species referred to in Article 4.1.6.2. from a country, *zone* or *compartment* not declared free from IHHN, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.6.3.

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CHAPTER 4.1.7.

CRAYFISH PLAGUE

Community comments

The community agrees with the proposed chapter, but would ask the OIE to consider the comments included under the specific Articles.

Article 4.1.7.1.

For the purposes of the *Aquatic Code*, crayfish plague means *infection* with *Aphanomyces astaci* Schikora. This organism is a member of a group commonly known as the water moulds (the Oomycetida). Common synonyms are listed in Chapter 4.1.7. of the *Aquatic Manual*.

Methods for surveillance and diagnosis are provided in the *Aquatic Manual*.

Article 4.1.7.2.

Scope

The recommendations in this Chapter apply to all species of crayfish in all three crayfish families (*Cambaridae*, *Astacidae*, and *Parastacidae*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Crayfish plague is most severe in European crayfish species including the noble crayfish (*Astacus astacus*), the white claw crayfish (*Austropotamobius pallipes*), stone crayfish (*Austropotamobius torrentium*), and the Turkish crayfish (*Astacus leptodactylus*). In general, the Parastacidae and the Astacidae (except *Pacifastacus*) are highly susceptible, while the Cambaridae are resistant to *disease*, but are potential carriers.

Article 4.1.7.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* of the *importing country* should not require any crayfish plague related conditions, regardless of the crayfish plague status of the *exporting country*, *zone* or *compartment*.

   a) For the species referred to in Article 4.1.7.2. for any purpose:

      i) commercially sterile canned products;

      ii) boiled products (e.g. cooked whole shrimp or tails, lobsters, crabs);

      iii) chemically extracted chitin;

      iv) crustacean meals or by-products made non-infectious by heating (>60°C for >5 minutes) or drying by-product (e.g. flame dried or sun dried);

      v) crustacean products made non-infectious during processing as dry feeds (e.g. pelleted or extruded feeds);

vi) biological samples preserved for diagnostic applications in such a manner as to inactivate the *A. astaci* (e.g. formalin or alcohol preserved samples);

vii) frozen products that have been subjected to -10°C or lower temperatures for at least 24 hours.

b) The following products destined for human consumption from species referred to in Article 4.1.7.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:

i) chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.);

ii) products that have been heat treated or dried (e.g. ready prepared meals) in a manner to ensure the inactivation of the pathogen.

For the *commodities* listed in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 4.1.7.2., other than those listed in point 1 of Article 4.1.7.3., the *Competent Authorities* of the *importing country* should require the conditions prescribed in Articles 4.1.7.7. to 4.1.7.11. relevant to the crayfish plague status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of any ~~other~~ *commodity* of a species not referred to in Article 4.1.7.2. but which could reasonably be expected to be a potential *A. astaci* carrier from an *exporting country*, *zone* or *compartment* not declared free of crayfish plague, the *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *A. astaci*, and the potential consequences, associated with the importation of the *commodity* prior to a decision. The *exporting country* should be informed of the outcome of this assessment.

Article 4.1.7.4.

Crayfish plague free country

A country may make a *self-declaration of freedom* from crayfish plague if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *water catchment* or with one or more other countries, it can only make a *self-declaration of freedom* from crayfish plague if all the areas covered by the shared water are declared crayfish plague free countries or *zones* (see Article 4.1.7.5.).

1. A country where none of the *susceptible species* referred to in Article 4.1.7.2. is present may make a *self-declaration of freedom* from crayfish plague when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 4.1.7.2. are present but there has never been any observed occurrence of the *disease* for at least the past 25 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from crayfish plague when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 25 years or where the

infection status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from crayfish plague when: Appendix XXI (contd)

a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 5 years without detection of *A. astaci*.

OR

4. A country that has previously made a *self-declaration of freedom* from crayfish plague but in which the *disease* is subsequently detected may not make a *self-declaration of freedom* from crayfish plague again until the following conditions have been met:

a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 5 years without detection of *A. astaci*.

In the meantime, part of the non-affected area may be declared a free *zone* provided that they meet the conditions in point 3 of Article 4.1.7.5.

Article 4.1.7.5.

Crayfish plague free zone or free compartment

The Community would argue that for certain compartments, disease free status could be regained if aquatic aquatic animal population is removed and disposed off, the establishment is properly disinfected and where appropriate fallowed and restocked with aquatic animals from a certified free source. The Community asks the OIE AAC to include that option as an alternative as a possible point 5. A proposal for a possible point 5 would be:

A compartment previously declared free from crayfish plague but in which the disease is detected may not be decl ared free from crayfish plague until the followings conditions have been met:

a) the requirements in point 4, or

b) if the compartment is supplied by water from a spring, borehole or other safe supply independent of the surrounding waters and is equipped with a barrier preventing migration of aquatic animals of susceptible species into the compartments or its water supply;

i) infected populations have been safely destroyed or removed from the infected compartment by means that minimise the risk of further spread of the disease, and appropriate disinfection procedures (see Aquatic Manual) have been completed and followed, when necessary by an appropriate fallowing period, and

ii) the compartment is repopulated with aquatic animals from a certified free population.

A *zone* or *compartment* within the *territory* of one or more countries not declared free from crayfish plague may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a crayfish plague free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 4.1.7.2. is present may be declared free from crayfish plague when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 4.1.7.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from crayfish plague when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from crayfish plague when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 2 years without detection of *A. astaci*.

OR

4. A *zone* previously declared free from crayfish plague but in which the *disease* is detected may not be declared free from crayfish plague again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *A. astaci*.

Article 4.1.7.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from crayfish plague following the provisions of points 1 or 2 of Articles 4.1.7.4. or 4.1.7.5. (as relevant) may maintain its status as crayfish plague free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from crayfish plague following the provisions of point 3 of Articles 4.1.7.4. or 4.1.7.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as crayfish plague free provided that conditions that are conducive to clinical expression of crayfish plague, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of crayfish plague, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 4.1.7.7.

Importation of live aquatic animals from a country, zone or compartment declared free from crayfish plague

When importing live *aquatic animals* of species referred to in Article 4.1.7.2. from a country, *zone* or *compartment* declared free from crayfish plague, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 4.1.7.4. or 4.1.7.5. (as applicable), the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from crayfish plague.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.3.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.7.3.

Article 4.1.7.8.

The Community would argue that point 2 and 3 of this article are beyond the scope of this part of the Code. See introductory remark.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from crayfish plague

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 4.1.7.2. from a country, *zone* or *compartment* not declared free from crayfish plague, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

   a) the direct delivery into and holding of the consignment in *quarantine* facilities;

   b) the continuous isolation of the imported live *aquatic animals* and their first generation progeny from the local environment;

   c) the treatment of all effluent and waste materials from the processing in a manner that ensures inactivation of *A. astaci*.

2. If the intention of the introduction is the establishment of new genetic lines, international standards, such as the Guidelines of the International Council for the Exploration of the Seas (ICES), should be followed.

3. For the purposes of the *Aquatic Code*, the ICES Guidelines may be summarised to the following main points:

   a) identify stock of interest (cultured or wild) in its current location;

   b) evaluate stock's health/*disease* history;

   c) take and test samples for *A. astaci*, pests and general health/*disease* status;

   d) import and quarantine in a secure facility a founder (F-0) population;

   e) produce F-1 generation from the F-0 stock in *quarantine*;

   f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *A. astaci* and perform general examinations for pests and general health/*disease* status;

   g) if *A. astaci* is not detected, pests are not present, and the general health/*disease* status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the

F-1 stock may be defined as crayfish plague free or specific pathogen free (SPF) for *A. astaci*;

h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.7.3.

Article 4.1.7.9.

Importation of live aquatic animals for human consumption from a country, zone or compartment not declared free from crayfish plague

When importing, for human consumption, live *aquatic animals* of species referred to in Article 4.1.7.2. from a country, *zone* or *compartment* not declared free from crayfish plague, the *Competent Authority* of the *importing country* should require that:

1. the consignment be delivered directly to and held in isolation until consumption; and
2. all effluent, dead *aquatic animals* and waste materials from the processing be treated in a manner that ensures inactivation of *A. astaci*.

Member Countries should consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.7.3.

Article 4.1.7.10.

Community comment

The recommendation in Article 4.1.7.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 4.1.7.9. To request animal health certificates for crustacean products, taking into account their intended use and the nature of the commodities, seems non-justifiable.

The Community would suggest the OIE to merge article 4.1.7.10 with article 4.1.7.11. The new article would read:

Importation of aquatic animal products

When importing *aquatic animal products* of species referred to in Article 4.1.7.2., the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 4.1.7.3.

mportation of aquatic animal products from a country, zone or compartment declared free from crayfish plague

When importing *aquatic animal products* of species referred to in Article 4.1.7.2. from a country, *zone* or *compartment* declared free from crayfish plague, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 4.1.7.4. or 4.1.7.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from crayfish plague.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.2.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.7.3.

Article 4.1.7.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from crayfish plague

When importing *aquatic animal products* of species referred to in Article 4.1.7.2. from a country, *zone* or *compartment* not declared free from crayfish plague, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.7.3.

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CHAPTER 4.1.9.

INFECTIOUS MYONECROSIS

Community comments

The community agrees with the proposed chapter, but would ask the OIE to consider the comments included under the specific Articles.

Article 4.1.9.1.

For the purposes of the *Aquatic Code*, infectious myonecrosis (IMN) means *infection* with infectious myonecrosis virus (IMNV). This virus is similar to members of the family *Totiviridae*.

Methods for surveillance and diagnosis are provided in the *Aquatic Manual*.

Article 4.1.9.2.

Scope

The recommendations in this Chapter apply to: Pacific white shrimp (*Penaeus vannamei*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 4.1.9.3.

Commodities

1. When authorising importation or transit of the following *commodities*, the *Competent Authorities* of the *importing country* should not require any IMN related conditions, regardless of the IMN status of the *exporting country*, *zone* or *compartment*.

   a) For the species referred to in Article 4.1.9.2. for any purpose:

      i) commercially sterile canned products;

      ii) boiled products (e.g. boiled whole shrimp or tails, lobsters, crabs);

      iii) chemically extracted chitin;

      iv) crustacean meals or by-products made non-infectious by heating or drying (e.g. flame dried or sun dried);

      v) crustacean products made non-infectious through processing as dry feeds (e.g. pelleted or extruded feeds);

      vi) biological samples preserved for diagnostic applications in such a manner as to inactivate the IMNV (e.g. formalin or alcohol preserved samples).

   b) The following products destined for human consumption from species referred to in Article 4.1.9.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:

      i) chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.);

ii) products that have been heat treated or dried (e.g. ready prepared meals) in a manner to ensure the inactivation of the pathogen.

For the *commodities* listed in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 4.1.9.2., other than those listed in point 1 of Article 4.1.9.3., the *Competent Authorities* of the *importing country* should require the conditions prescribed in Articles 4.1.9.7. to 4.1.9.11. relevant to the IMN status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of any ~~other~~ *commodity* of a species not referred to in Article 4.1.9.2. but which could reasonably be expected to be a potential IMNV carrier from an *exporting country*, *zone* or *compartment* not declared free of IMN, the *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of IMNV, and the potential consequences, associated with the importation of the *commodity* prior to a decision. The *exporting country* should be informed of the outcome of this assessment.

Article 4.1.9.4.

Infectious myonecrosis free country

A country may make a *self-declaration of freedom* from IMN if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from IMN if all the areas covered by the shared water are declared IMN free countries or *zones* (see Article 4.1.9.5.).

1. A country where none of the *susceptible species* referred to in Article 4.1.9.2. is present may make a *self-declaration of freedom* from IMN when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 4.1.9.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from IMN when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from IMN when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of IMNV.

OR

4. A country that has previously made a *self-declaration of freedom* from IMN but in which the *disease* is subsequently detected may not make a *self-declaration of freedom* from IMN again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of IMNV.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that they meet the conditions in point 3 of Article 4.1.9.5.

Article 4.1.9.5.

The Community would argue that for certain compartments, disease free status could be regained if aquatic aquatic animal population is removed and disposed off, the establishment is properly disinfected and where appropriate fallowed and restocked with aquatic animals from a certified free source. The Community asks the OIE AAC to include that option as an alternative as a possible point 5. A proposal for a possible point 5 would be:

A compartment previously declared free from IMD but in which the disease is detected may not be decl ared free from IMD until the followings conditions have been met:

a) the requirements in point 4, or

b) if the compartment is supplied by water from a spring, borehole or other safe supply independent of the surrounding waters and is equipped with a barrier preventing migration of aquatic animals of susceptible species into the compartments or its water supply;

i) infected populations have been safely destroyed or removed from the infected compartment by means that minimise the risk of further spread of the disease, and appropriate disinfection procedures (see Aquatic Manual) have been completed, and followed, when necessary by an appropriate fallowing period, and

ii) the compartment is repopulated with aquatic animals from a certified free population.

Infectious myonecrosis free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from IMN may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared an IMN free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 4.1.9.2. is present may be declared free from IMN when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 4.1.9.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from IMN when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from IMN when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 2 years without detection of IMNV.

OR

4. A *zone* previously declared free from IMN but in which the *disease* is detected may not be declared free from IMN again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of IMNV.

Article 4.1.9.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from IMN following the provisions of points 1 or 2 of Articles 4.1.9.4. or 4.1.9.5. (as relevant) may maintain its status as IMN free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from IMN following the provisions of point 3 of Articles 4.1.9.4. or 4.1.9.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as IMN free provided that conditions that are conducive to clinical expression of IMN, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of IMN, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 4.1.9.7.

Importation of live aquatic animals from a country, zone or compartment declared free from infectious myonecrosis

When importing live *aquatic animals* of species referred to in Article 4.1.9.2. from a country, *zone* or *compartment* declared free from IMN, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 4.1.9.4. or 4.1.9.5. (as applicable), the place of production of the ***commodity*** ~~consignment~~ is a country, *zone* or *compartment* declared free from IMN.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.3.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.9.3.

Article 4.1.9.8.

The Community would argue that point 2 and 3 of this article are beyond the scope of this part of the Code. See introductory remark.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from infectious myonecrosis

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 4.1.9.2. from a country, *zone* or *compartment* not declared free from IMN, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:
   a) the direct delivery into and holding of the consignment in *quarantine* facilities;
   b) the continuous isolation of the imported live *aquatic animals* and their first generation progeny from the local environment;
   c) the treatment of all effluent and waste materials from the processing in a manner that ensures inactivation of IMNV.
2. If the intention of the introduction is the establishment of new genetic lines, international standards, such as the Guidelines of the International Council for the Exploration of the Seas (ICES), should be followed.
3. For the purposes of the *Aquatic Code*, the ICES Guidelines may be summarised to the following main points:
   a) identify stock of interest (cultured or wild) in its current location;
   b) evaluate stock's health/*disease* history;
   c) take and test samples for IMNV, pests and general health/*disease* status;
   d) import and quarantine in a secure facility a founder (F-0) population;
   e) produce F-1 generation from the F-0 stock in *quarantine*;
   f) culture F-1 stock and at critical times in its development (life cycle) sample and test for IMNV and perform general examinations for pests and general health/*disease* status;
   g) if IMNV is not detected, pests are not present, and the general health/*disease* status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as IMN free or specific pathogen free (SPF) for IMNV;
   h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.9.3.

Article 4.1.9.9.

Importation of live aquatic animals for human consumption from a country, zone or compartment not declared free from infectious myonecrosis

When importing, for human consumption, live *aquatic animals* of species referred to in Article 4.1.9.2. from a country, *zone* or *compartment* not declared free from IMN, the *Competent Authority* of the *importing country* should require that:

1. the consignment be delivered directly to and held in isolation until consumption; and
2. all effluent, dead *aquatic animals* and waste materials from the processing be treated in a manner that ensures inactivation of IMNV.

Member Countries should consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.9.3.

Article 4.1.9.10.

Community comment

The recommendation in Article 4.1.9.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 4.1.9.9. To request animal health certificates for crustacean products, taking into account their intended use and the nature of the commodities, seems non-justifiable.

The Community would suggest the OIE to merge article 4.1.9.10 with article 4.1.9.11. The new article would read:

Importation of aquatic animal products

When importing *aquatic animal products* of species referred to in Article 4.1.9.2., the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 4.1.9.3.

Importation of aquatic animal products from a country, zone or compartment declared free from infectious myonecrosis

When importing *aquatic animal products* of species referred to in Article 4.1.9.2. from a country, *zone* or *compartment* declared free from IMN, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 4.1.9.4. or 4.1.9.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from IMN.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.2.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.9.3.

Article 4.1.9.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from infectious myonecrosis

When importing *aquatic animal products* of species referred to in Article 4.1.9.2. from a country, *zone* or *compartment* not declared free from IMN, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.9.3.

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CHAPTER 4.1.10.

NECROTISING HEPATOPANCREATITIS

Community comments

The community agrees with the proposed chapter, but would ask the OIE to consider the comments included under the specific Articles.

Article 4.1.10.1.

For the purposes of the *Aquatic Code*, necrotising hepatopancreatitis (NHP) means *infection* with necrotising hepatopancreatitis bacteria (NHP-B). This obligate intracellular bacterium is a member of the order α-Proteobacteria.

Methods for surveillance and diagnosis are provided in the *Aquatic Manual*.

Article 4.1.10.2.

Scope

The recommendations in this Chapter apply to: Pacific white shrimp (*Penaeus vannamei*), blue shrimp (*P. stylirostris*), northern white shrimp (*P. setiferus*) and northern brown shrimp (*P. aztecus*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 4.1.10.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* of the *importing country* should not require any NHP related conditions, regardless of the NHP status of the *exporting country*, *zone* or *compartment*.

   a) For the species referred to in Article 4.1.10.2. for any purpose:

      i) commercially sterile canned products;

      ii) boiled products (e.g. boiled whole shrimp or tails, lobsters, crabs);

      iii) chemically extracted chitin;

      iv) crustacean meals or by-products made non-infectious by heating or drying (e.g. flame dried or sun dried);

      v) crustacean products made non-infectious through processing as dry feeds (e.g. pelleted or extruded feeds);

      vi) biological samples preserved for diagnostic applications in such a manner as to inactivate the NHP-B (e.g. formalin or alcohol preserved samples);

vii) frozen products.

b) The following products destined for human consumption from species referred to in Article 4.1.10.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:

i) chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.);

ii) products that have been heat treated or dried (e.g. ready prepared meals) in a manner to ensure the inactivation of the pathogen;

iii) de-headed and ~~de-veined~~ "de-veined" (intestine removed) shrimp tails.

For the *commodities* listed in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 4.1.10.2., other than those listed in point 1 of Article 4.1.10.3., the *Competent Authorities* of the *importing country* should require the conditions prescribed in Articles 4.1.10.7. to 4.1.10.11. relevant to the NHP status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of any ~~other~~ *commodity* of a species not referred to in Article 4.1.10.2. but which could reasonably be expected to be a potential NHP-B carrier from an *exporting country*, *zone* or *compartment* not declared free of NHP, the *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of NHP-B, and the potential consequences, associated with the importation of the *commodity* prior to a decision. The *exporting country* should be informed of the outcome of this assessment.

Article 4.1.10.4.

Necrotising hepatopancreatitis free country

A country may make a *self-declaration of freedom* from NHP if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from NHP if all the areas covered by the shared water are declared NHP free countries or zones (see Article 4.1.10.5.).

1. A country where none of the *susceptible species* referred to in Article 4.1.10.2. is present may make a *self-declaration of freedom* from NHP when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 4.1.10.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from NHP when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from NHP when:

a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of NHP-B.

OR

4. A country that has previously made a *self-declaration of freedom* from NHP but in which the *disease* is subsequently detected may not make a *self-declaration of freedom* from NHP again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of NHP-B.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that they meet the conditions in point 3 of Article 4.1.10.5.

Article 4.1.10.5.

Necrotising hepatopancreatitis free zone or free compartment

The Community would argue that for certain compartments, disease free status could be regained if aquatic aquatic animal population is removed and disposed off, the establishment is properly disinfected and where appropriate fallowed and restocked with aquatic animals from a certified free source. The Community asks the OIE AAC to include that option as an alternative as a possible point 5. A proposal for a possible point 5 would be:

A compartment previously declared free from NHP but in which the disease is detected may not be decl ared free from NHPuntil the followings conditions have been met:

a) the requirements in point 4, or

b) if the compartment is supplied by water from a spring, borehole or other safe supply independent of the surrounding waters and is equipped with a barrier preventing migration of aquatic animals of susceptible species into the compartments or its water supply;

i) infected populations have been safely destroyed or removed from the infected compartment by means that minimise the risk of further spread of the disease, and appropriate disinfection procedures (see Aquatic Manual) have been completed and followed, when necessary by an appropriate fallowing period, and

ii) the compartment is repopulated with aquatic animals from a certified free population.

A *zone* or *compartment* within the *territory* of one or more countries not declared free from NHP may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a NHP free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 4.1.10.2. is present may be declared free from NHP when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 4.1.10.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from NHP when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from NHP when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 2 years without detection of NHP-B.

OR

4. A *zone* previously declared free from NHP but in which the *disease* is detected may not be declared free from NHP again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of NHP-B.

Article 4.1.10.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from NHP following the provisions of points 1 or 2 of Articles 4.1.10.4. or 4.1.10.5. (as relevant) may maintain its status as NHP free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from NHP following the provisions of point 3 of Articles 4.1.10.4. or 4.1.10.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as NHP free provided that conditions that are conducive to clinical expression of NHP, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of NHP, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 4.1.10.7.

Importation of live aquatic animals from a country, zone or compartment declared free from

necrotising hepatopancreatitis

When importing live *aquatic animals* of species referred to in Article 4.1.10.2. from a country, *zone* or *compartment* declared free from NHP, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 4.1.10.4. or 4.1.10.5. (as applicable), the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from NHP.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.3.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.10.3.

Article 4.1.10.8.

The Community would argue that point 2 and 3 of this article are beyond the scope of this part of the Code. See introductory remark.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from necrotising hepatopancreatitis

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 4.1.10.2. from a country, *zone* or *compartment* not declared free from NHP, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:
   a) the direct delivery into and holding of the consignment in *quarantine* facilities;
   b) the continuous isolation of the imported live *aquatic animals* and their first generation progeny from the local environment;
   c) the treatment of all effluent and waste materials from the processing in a manner that ensures inactivation of NHP-B.
2. If the intention of the introduction is the establishment of new genetic lines, international standards, such as the Guidelines of the International Council for the Exploration of the Seas (ICES), should be followed.
3. For the purposes of the *Aquatic Code*, the ICES Guidelines may be summarised to the following main points:
   a) identify stock of interest (cultured or wild) in its current location;
   b) evaluate stock's health/*disease* history;
   c) take and test samples for NHP-B, pests and general health/*disease* status;
   d) import and quarantine in a secure facility a founder (F-0) population;
   e) produce F-1 generation from the F-0 stock in *quarantine*;
   f) culture F-1 stock and at critical times in its development (life cycle) sample and test for NHP-B and perform general examinations for pests and general health/*disease* status;
   g) if NHP-B is not detected, pests are not present, and the general health/*disease* status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as NHP free or specific pathogen free (SPF) for NHP-B;
   h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or

compartment.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.10.3.

Article 4.1.10.9.

Importation of live aquatic animals for human consumption from a country, zone or compartment not declared free from necrotising hepatopancreatitis

When importing, for human consumption, live *aquatic animals* of species referred to in Article 4.1.10.2. from a country, *zone* or *compartment* not declared free from NHP, the *Competent Authority* of the *importing country* should require that:

1. the consignment be delivered directly to and held in isolation until consumption; and
2. all effluent, dead *aquatic animals* and waste materials from the processing be treated in a manner that ensures inactivation of NHP-B.

Member Countries should consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.10.3.

Article 4.1.10.10.

Community comment

The recommendation in Article 4.1.10.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 4.1.10.9. To request animal health certificates for crustacean products, taking into account their intended use and the nature of the commodities, seems non-justifiable.

The Community would suggest the OIE to merge article 4.1.10.10 with article 4.1.10.11. The new article would read:

Importation of aquatic animal products

When importing *aquatic animal products* of species referred to in Article 4.1.10.2., the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 4.1.10.3.

Importation of aquatic animal products from a country, zone or compartment declared free from necrotising hepatopancreatitis

When importing *aquatic animal products* of species referred to in Article 4.1.10.2. from a country, *zone* or *compartment* declared free from NHP, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 4.1.10.4. or 4.1.10.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from NHP.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.2.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.10.3.

Article 4.1.10.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from necrotising hepatopancreatitis

When importing *aquatic animal products* of species referred to in Article 4.1.10.2. from a country, *zone* or *compartment* not declared free from NHP, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.10.3.

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CHAPTER 4.1.11.

WHITE TAIL DISEASE

Community comments

The community agrees with the proposed chapter, but would ask the OIE to consider the comments included under the specific Articles.

Article 4.1.11.1.

For the purposes of the *Aquatic Code*, white tail disease (WTD) means *infection* with macrobrachium nodavirus (MrNV). This virus has yet to be formally classified.

Methods for surveillance and diagnosis are provided in the *Aquatic Manual*.

Article 4.1.11.2.

Scope

The recommendations in this Chapter apply to: the giant fresh water prawn (*Macrobrachium rosenbergii*). Other common names are listed in the *Aquatic Manual*. These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 4.1.11.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* of the *importing country* should not require any WTD related conditions, regardless of the WTD status of the *exporting country*, *zone* or *compartment*.

   a) For the species referred to in Article 4.1.11.2. for any purpose:

      i) commercially sterile canned products;

      ii) boiled products (e.g. boiled whole shrimp or tails, lobsters, crabs);

      iii) chemically extracted chitin;

      iv) crustacean meals or by-products made non-infectious by heating or drying (e.g. flame dried or sun dried);

      v) crustacean products made non-infectious through processing as dry feeds (e.g. pelleted or extruded feeds);

      vi) biological samples preserved for diagnostic applications in such a manner as to inactivate the MrNV (e.g. formalin or alcohol preserved samples).

   b) The following products destined for human consumption from species referred to in Article 4.1.11.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:

i) chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.);

ii) products that have been heat treated or dried (e.g. ready prepared meals) in a manner to ensure the inactivation of the pathogen.

For the *commodities* listed in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 4.1.11.2., other than those listed in point 1 of Article 4.1.11.3., the *Competent Authorities* of the *importing country* should require the conditions prescribed in Articles 4.1.11.7. to 4.1.11.11. relevant to the WTD status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of any ~~other~~ *commodity* of a species not referred to in Article 4.1.11.2. but which could reasonably be expected to be a potential MrNV carrier from an *exporting country*, *zone* or *compartment* not declared free of WTD, the *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of MrNV, and the potential consequences, associated with the importation of the *commodity* prior to a decision. The *exporting country* should be informed of the outcome of this assessment.

Article 4.1.11.4.

White tail disease free country

A country may make a *self-declaration of freedom* from WTD if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from WTD if all the areas covered by the shared water are declared WTD free countries or *zones* (see Article 4.1.11.5.).

1. A country where none of the *susceptible species* referred to in Article 4.1.11.2. is present may make a *self-declaration of freedom* from WTD when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 4.1.11.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from WTD when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from WTD when:

a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in

place for at least the last 2 years without detection of MrNV.

OR

4. A country that has previously made a *self-declaration of freedom* from WTD but in which the *disease* is subsequently detected may not make a *self-declaration of freedom* from WTD again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of MrNV.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that they meet the conditions in point 3 of Article 4.1.11.5.

Article 4.1.11.5.

White tail disease free zone or free compartment

The Community would argue that for certain compartments, disease free status could be regained if aquatic aquatic animal population is removed and disposed off, the establishment is properly disinfected and where appropriate fallowed and restocked with aquatic animals from a certified free source. The Community asks the OIE AAC to include that option as an alternative as a possible point 5. A proposal for a possible point 5 would be:

A compartment previously declared free from WTD but in which the disease is detected may not be decl ared free from WTD until the followings conditions have been met:

a) the requirements in point 4, or

b) if the compartment is supplied by water from a spring, borehole or other safe supply independent of the surrounding waters and is equipped with a barrier preventing migration of aquatic animals of susceptible species into the compartments or its water supply;

i) infected populations have been safely destroyed or removed from the infected compartment by means that minimise the risk of further spread of the disease, and appropriate disinfection procedures (see Aquatic Manual) have been completed, and followed, when necessary by an appropriate fallowing period, and

ii) the compartment is repopulated with aquatic animals from a certified free population

A *zone* or *compartment* within the *territory* of one or more countries not declared free from WTD may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a WTD free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 4.1.11.2. is present may be declared free from WTD when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 4.1.11.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from WTD when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from WTD when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 2 years without detection of MrNV.

OR

4. A *zone* previously declared free from WTD but in which the *disease* is detected may not be declared free from WTD again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of MrNV.

Article 4.1.11.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from WTD following the provisions of points 1 or 2 of Articles 4.1.11.4. or 4.1.11.5. (as relevant) may maintain its status as WTD free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from WTD following the provisions of point 3 of Articles 4.1.11.4. or 4.1.11.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as WTD free provided that conditions that are conducive to clinical expression of WTD, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of WTD, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 4.1.11.7.

Importation of live aquatic animals from a country, zone or compartment declared free from

white tail disease

When importing live *aquatic animals* of species referred to in Article 4.1.11.2. from a country, *zone* or *compartment* declared free from WTD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 4.1.11.4. or 4.1.11.5. (as applicable), the place of production of the *commodity* is a country, *zone* or *compartment* declared free from WTD.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.3.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.11.3.

Article 4.1.11.8.

The Community would argue that point 2 and 3 of this article are beyond the scope of this part of the Code. See introductory remark.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from white tail disease

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 4.1.11.2. from a country, *zone* or *compartment* not declared free from WTD, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

   a) the direct delivery into and holding of the consignment in *quarantine* facilities;

   b) the continuous isolation of the imported live *aquatic animals* and their first generation progeny from the local environment;

   c) the treatment of all effluent and waste materials from the processing in a manner that ensures inactivation of MrNV.

2. If the intention of the introduction is the establishment of new genetic lines, international standards, such as the Guidelines of the International Council for the Exploration of the Seas (ICES), should be followed.

3. For the purposes of the *Aquatic Code*, the ICES Guidelines may be summarised to the following main points:

   a) identify stock of interest (cultured or wild) in its current location;

   b) evaluate stock's health/*disease* history;

   c) take and test samples for MrNV, pests and general health/*disease* status;

   d) import and quarantine in a secure facility a founder (F-0) population;

   e) produce F-1 generation from the F-0 stock in *quarantine*;

   f) culture F-1 stock and at critical times in its development (life cycle) sample and test for MrNV and perform general examinations for pests and general health/*disease* status;

   g) if MrNV is not detected, pests are not present, and the general health/*disease* status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as WTD free or specific pathogen free (SPF) for MrNV;

   h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or

compartment.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.11.3.

Article 4.1.11.9.

Importation of live aquatic animals for human consumption from a country, zone or compartment not declared free from white tail disease

When importing, for human consumption, live *aquatic animals* of species referred to in Article 4.1.11.2. from a country, *zone* or *compartment* not declared free from WTD, the *Competent Authority* of the *importing country* should require that:

1. the consignment be delivered directly to and held in isolation until consumption; and
2. all effluent, dead *aquatic animals* and waste materials from the processing be treated in a manner that ensures inactivation of MrNV.

Member Countries should consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.11.3.

Article 4.1.11.10.

Community comment

The recommendation in Article 4.1.11.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 4.1.11.9. To request animal health certificates for crustacean products, taking into account their intended use and the nature of the commodities, seems non-justifiable.

The Community would suggest the OIE to merge article 4.1.11.10 with article 4.1.11.11. The new article would read:

Importation of aquatic animal products

When importing *aquatic animal products* of species referred to in Article 4.1.11.2., the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 4.1.11.3.

Importation of aquatic animal products from a country, zone or compartment declared free from white tail disease

When importing *aquatic animal products* of species referred to in Article 4.1.11.2. from a country, *zone* or *compartment* declared free from WTD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 4.1.11.4. or 4.1.11.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from WTD.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.2.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.11.3.

Article 4.1.11.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from white tail disease

When importing *aquatic animal products* of species referred to in Article 4.1.11.2. from a country, *zone* or *compartment* not declared free from WTD, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.11.3.

CHAPTER 4.1.12.

HEPATOPANCREATIC PARVOVIRUS DISEASE

Community comments

The community agrees with the proposed chapter, but would ask the OIE to consider the comments included under the specific Articles.

Article 4.1.12.1.

For the purposes of the *Aquatic Code*, hepatopancreatic parvovirus disease (HPVD) means *infection* with hepatopancreatic parvovirus (HPV). It is considered to be a member of the subfamily of the *Densovirinae* in the family *Parvoviridae*.

Methods for surveillance and diagnosis are provided in the *Aquatic Manual*.

Article 4.1.12.2.

Scope

The recommendations in this Chapter apply to: Indian white shrimp (*Penaeus indicus*), black tiger shrimp (*Penaeus monodon*), Pacific white shrimp (*Penaeus vannamei*) and Pacific blue shrimp (*P. stylirostris*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 4.1.12.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* of the *importing country* should not require any HPVD related conditions, regardless of the HPVD status of the *exporting country*, *zone* or *compartment*.

   a) For the species referred to in Article 4.1.12.2. for any purpose:

      i) commercially sterile canned products;

      ii) boiled products (e.g. boiled whole shrimp or tails, lobsters, crabs);

      iii) chemically extracted chitin;

      iv) crustacean meals or by-products made non-infectious by heating or drying (e.g. flame dried or sun dried);

      v) crustacean products made non-infectious through processing as dry feeds (e.g. pelleted or extruded feeds);

      vi) biological samples preserved for diagnostic applications in such a manner as to inactivate the HPV (e.g. formalin or alcohol preserved samples).

b) The following products destined for human consumption from species referred to in Article 4.1.12.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:

i) chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.);

ii) products that have been heat treated or dried (e.g. ready prepared meals) in a manner to ensure the inactivation of the pathogen;

iii) de-headed and "de-veined" (intestine removed) shrimp tails.

For the *commodities* listed in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 4.1.12.2., other than those listed in point 1 of Article 4.1.12.3., the *Competent Authorities* of the *importing country* should require the conditions prescribed in Articles 4.1.12.7. to 4.1.12.11. relevant to the HPVD status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of any ~~other~~ *commodity* of a species not referred to in Article 4.1.12.2. but which could reasonably be expected to be a potential HPV carrier from an *exporting country*, *zone* or *compartment* not declared free of HPVD, the *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of HPV, and the potential consequences, associated with the importation of the *commodity* prior to a decision. The *exporting country* should be informed of the outcome of this assessment.

Article 4.1.12.4.

Hepatopancreatic parvovirus disease free country

A country may make a *self-declaration of freedom* from HPVD if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from HPVD if all the areas covered by the shared water are declared HPVD free countries or *zones* (see Article 4.1.12.5.).

1. A country where none of the *susceptible species* referred to in Article 4.1.12.2. is present may make a *self-declaration of freedom* from HPVD when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 4.1.12.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from HPVD when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from HPVD when:

a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of HPV.

OR

4. A country that has previously made a *self-declaration of freedom* from HPVD but in which the *disease* is subsequently detected may not make a *self-declaration of freedom* from HPVD again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of HPV.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that they meet the conditions in point 3 of Article 4.1.12.5.

Article 4.1.12.5.

Hepatopancreatic parvovirus disease free zone or free compartment

The Community would argue that for certain compartments, disease free status could be regained if aquatic aquatic animal population is removed and disposed off, the establishment is properly disinfected and where appropriate fallowed and restocked with aquatic animals from a certified free source. The Community asks the OIE AAC to include that option as an alternative as a possible point 5. A proposal for a possible point 5 would be:

A compartment previously declared free from HPVD but in which the disease is detected may not be decl ared free from HPVD until the followings conditions have been met:

a) the requirements in point 4, or

b) if the compartment is supplied by water from a spring, borehole or other safe supply independent of the surrounding waters and is equipped with a barrier preventing migration of aquatic animals of susceptible species into the compartments or its water supply;

i) infected populations have been safely destroyed or removed from the infected compartment by means that minimise the risk of further spread of the disease, and appropriate disinfection procedures (see Aquatic Manual) have been completed, and followed, when necessary by an appropriate fallowing period, and

ii) the compartment is repopulated with aquatic animals from a certified free population

A *zone* or *compartment* within the *territory* of one or more countries not declared free from HPVD may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a HPVD free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 4.1.12.2. is present may be declared free from HPVD when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 4.1.12.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from HPVD when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from HPVD when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 2 years without detection of HPV.

OR

4. A *zone* previously declared free from HPVD but in which the *disease* is detected may not be declared free from HPVD again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of HPV.

Article 4.1.12.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from HPVD following the provisions of points 1 or 2 of Articles 4.1.12.4. or 4.1.12.5. (as relevant) may maintain its status as HPVD free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from HPVD following the provisions of point 3 of Articles 4.1.12.4. or 4.1.12.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as HPVD free provided that conditions that are conducive to clinical expression of HPVD, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of HPVD, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 4.1.12.7.

Importation of live aquatic animals from a country, zone or compartment declared free from hepatopancreatic parvovirus disease

When importing live *aquatic animals* of species referred to in Article 4.1.12.2. from a country, *zone* or *compartment* declared free from HPVD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 4.1.12.4. or 4.1.12.5. (as applicable), the place of production of the *commodity* is a country, *zone* or *compartment* declared free from HPVD.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.3.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.12.3.

Article 4.1.12.8.

The Community would argue that point 2 and 3 of this article are beyond the scope of this part of the Code. See introductory remark.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from hepatopancreatic parvovirus disease

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 4.1.12.2. from a country, *zone* or *compartment* not declared free from HPVD, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

   a) the direct delivery into and holding of the consignment in *quarantine* facilities;

   b) the continuous isolation of the imported live *aquatic animals* and their first generation progeny from the local environment;

   c) the treatment of all effluent and waste materials from the processing in a manner that ensures inactivation of HPV.

2. If the intention of the introduction is the establishment of new genetic lines, international standards, such as the Guidelines of the International Council for the Exploration of the Seas (ICES), should be followed.

3. For the purposes of the *Aquatic Code*, the ICES Guidelines may be summarised to the following main points:

   a) identify stock of interest (cultured or wild) in its current location;

   b) evaluate stock's health/*disease* history;

   c) take and test samples for HPV, pests and general health/*disease* status;

   d) import and quarantine in a secure facility a founder (F-0) population;

   e) produce F-1 generation from the F-0 stock in *quarantine*;

   f) culture F-1 stock and at critical times in its development (life cycle) sample and test for HPV and perform general examinations for pests and general health/*disease* status;

   g) if HPV is not detected, pests are not present, and the general health/*disease* status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as HPVD free or specific pathogen free (SPF) for HPV;

h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.12.3.

Article 4.1.12.9.

Importation of live aquatic animals for human consumption from a country, zone or compartment not declared free from hepatopancreatic parvovirus disease

When importing, for human consumption, live *aquatic animals* of species referred to in Article 4.1.12.2. from a country, *zone* or *compartment* not declared free from HPVD, the *Competent Authority* of the *importing country* should require that:

1. the consignment be delivered directly to and held in isolation until consumption; and
2. all effluent, dead *aquatic animals* and waste materials from the processing be treated in a manner that ensures inactivation of HPV.

Member Countries should consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.12.3.

Article 4.1.12.10.

Community comment

The recommendation in Article 4.1.12.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 4.1.12.9. To request animal health certificates for crustacean products, taking into account their intended use and the nature of the commodities, seems non-justifiable.

The Community would suggest the OIE to merge article 4.1.12.10 with article 4.1.12.11. The new article would read:

Importation of aquatic animal products

When importing *aquatic animal products* of species referred to in Article 4.1.12.2., the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 4.12.6.3.

Importation of aquatic animal products from a country, zone or compartment declared free from hepatopancreatic parvovirus disease

When importing *aquatic animal products* of species referred to in Article 4.1.12.2. from a country, *zone* or *compartment* declared free from HPVD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 4.1.12.4. or 4.1.12.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from HPVD.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.2.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.12.3.

Article 4.1.12.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from hepatopancreatic parvovirus disease

When importing *aquatic animal products* of species referred to in Article 4.1.12.2. from a country, *zone* or *compartment* not declared free from HPVD, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.12.3.

CHAPTER 4.1.13.

MOURILYAN VIRUS DISEASE

Community comments

The community agrees with the proposed chapter, but would ask the OIE to consider the comments included under the specific Articles.

Article 4.1.13.1.

For the purposes of the *Aquatic Code*, Mourilyan virus disease (MoVD) means *infection* with infection with Mourilyan virus (MoV). This virus is similar to members of the *Bunyaviridae*, but has yet to be formally classified.

Methods for surveillance and diagnosis are provided in the *Aquatic Manual*.

Article 4.1.13.2.

Scope

The recommendations in this Chapter apply to: black tiger shrimp (*Penaeus monodon*) and kuruma shrimp (*Penaeus japonicus*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 4.1.13.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* of the *importing country* should not require any MoVD related conditions, regardless of the MoVD status of the *exporting country*, *zone* or *compartment*.

   a) For the species referred to in Article 4.1.13.2. for any purpose:

      i) commercially sterile canned products;

      ii) boiled products (e.g. boiled whole shrimp or tails, lobsters, crabs);

      iii) chemically extracted chitin;

      iv) crustacean meals or by-products made non-infectious by heating or drying (e.g. flame dried or sun dried);

      v) crustacean products made non-infectious through processing as dry feeds (e.g. pelleted or extruded feeds);

      vi) biological samples preserved for diagnostic applications in such a manner as to inactivate the MoV (e.g. formalin or alcohol preserved samples).

b) The following products destined for human consumption from species referred to in Article 4.1.13.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:

i) chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.);

ii) products that have been heat treated or dried (e.g. ready prepared meals) in a manner to ensure the inactivation of the pathogen.

For the *commodities* listed in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 4.1.13.2., other than those listed in point 1 of Article 4.1.13.3., the *Competent Authorities* of the *importing country* should require the conditions prescribed in Articles 4.1.13.7. to 4.1.13.11. relevant to the MoVD status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of any ~~other~~ *commodity* of a species not referred to in Article 4.1.13.2. but which could reasonably be expected to be a potential MoV carrier from an *exporting country*, *zone* or *compartment* not declared free of MoVD, the *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of MoV, and the potential consequences, associated with the importation of the *commodity* prior to a decision. The *exporting country* should be informed of the outcome of this assessment.

Article 4.1.13.4.

Mourilyan virus disease free country

A country may make a *self-declaration of freedom* from MoVD if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from MoVD if all the areas covered by the shared water are declared MoVD free countries or *zones* (see Article 4.1.13.5.).

1. A country where none of the *susceptible species* referred to in Article 4.1.13.2. is present may make a *self-declaration of freedom* from MoVD when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 4.1.13.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from MoVD when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from MoVD when:

a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of MoV.

OR

4. A country that has previously made a *self-declaration of freedom* from MoVD but in which the *disease* is subsequently detected may not make a *self-declaration of freedom* from MoVD again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of MoV.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that they meet the conditions in point 3 of Article 4.1.13.5.

Article 4.1.13.5.

Mourilyan virus disease free zone or free compartment

The Community would argue that for certain compartments, disease free status could be regained if aquatic aquatic animal population is removed and disposed off, the establishment is properly disinfected and where appropriate fallowed and restocked with aquatic animals from a certified free source. The Community asks the OIE AAC to include that option as an alternative as a possible point 5. A proposal for a possible point 5 would be:

A compartment previously declared free from MoVD but in which the disease is detected may not be decl ared free from MoVD until the followings conditions have been met:

a) the requirements in point 4, or

b) if the compartment is supplied by water from a spring, borehole or other safe supply independent of the surrounding waters and is equipped with a barrier preventing migration of aquatic animals of susceptible species into the compartments or its water supply;

i) infected populations have been safely destroyed or removed from the infected compartment by means that minimise the risk of further spread of the disease, and appropriate disinfection procedures (see Aquatic Manual) have been completed and followed, when necessary by an appropriate fallowing period, and

ii) the compartment is repopulated with aquatic animals from a certified free population

A *zone* or *compartment* within the *territory* of one or more countries not declared free from MoVD may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a MoVD free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 4.1.13.2. is present may be declared free from MoVD when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 4.1.13.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from MoVD when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from MoVD when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 2 years without detection of MoV.

OR

4. A *zone* previously declared free from MoVD but in which the *disease* is detected may not be declared free from MoVD again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of MoV.

Article 4.1.13.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from MoVD following the provisions of points 1 or 2 of Articles 4.1.13.4. or 4.1.13.5. (as relevant) may maintain its status as MoVD free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from MoVD following the provisions of point 3 of Articles 4.1.13.4. or 4.1.13.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as MoVD free provided that conditions that are conducive to clinical expression of MoVD, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of MoVD, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 4.1.13.7.

Importation of live aquatic animals from a country, zone or compartment declared free from

Mourilyan virus disease

When importing live *aquatic animals* of species referred to in Article 4.1.13.2. from a country, *zone* or *compartment* declared free from MoVD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 4.1.13.4. or 4.1.13.5. (as applicable), the place of production of the *commodity* is a country, *zone* or *compartment* declared free from MoVD.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.3.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.13.3.

Article 4.1.13.8.

The Community would argue that point 2 and 3 of this article are beyond the scope of this part of the Code. See introductory remark.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from Mourilyan virus disease

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 4.1.13.2. from a country, *zone* or *compartment* not declared free from MoVD, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

   a) the direct delivery into and holding of the consignment in *quarantine* facilities;

   b) the continuous isolation of the imported live *aquatic animals* and their first generation progeny from the local environment;

   c) the treatment of all effluent and waste materials from the processing in a manner that ensures inactivation of MoV.

2. If the intention of the introduction is the establishment of new genetic lines, international standards, such as the Guidelines of the International Council for the Exploration of the Seas (ICES), should be followed.

3. For the purposes of the *Aquatic Code*, the ICES Guidelines may be summarised to the following main points:

   a) identify stock of interest (cultured or wild) in its current location;

   b) evaluate stock's health/*disease* history;

   c) take and test samples for MoV, pests and general health/*disease* status;

   d) import and quarantine in a secure facility a founder (F-0) population;

   e) produce F-1 generation from the F-0 stock in *quarantine*;

   f) culture F-1 stock and at critical times in its development (life cycle) sample and test for MoV and perform general examinations for pests and general health/*disease* status;

   g) if MoV is not detected, pests are not present, and the general health/*disease* status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as MoVD free or specific pathogen free (SPF) for MoV;

   h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or

compartment.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.13.3.

Article 4.1.13.9.

Importation of live aquatic animals for human consumption from a country, zone or compartment not declared free from Mourilyan virus disease

When importing, for human consumption, live *aquatic animals* of species referred to in Article 4.1.13.2. from a country, *zone* or *compartment* not declared free from MoVD, the *Competent Authority* of the *importing country* should require that:

1. the consignment be delivered directly to and held in isolation until consumption; and
2. all effluent, dead *aquatic animals* and waste materials from the processing be treated in a manner that ensures inactivation of MoV.

Member Countries should consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.13.3.

Article 4.1.13.10.

Community comment

The recommendation in Article 4.1.13 10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 4.1.13.9. To request animal health certificates for crustacean products, taking into account their intended use and the nature of the commodities, seems non-justifiable

The Community would suggest the OIE to merge article 4.1.13.10 with article 4.1.13.11. The new article would read:

Importation of aquatic animal products

When importing *aquatic animal products* of species referred to in Article 4.1.13.2., the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 4.1.13.3.

Importation of aquatic animal products from a country, zone or compartment declared free from Mourilyan virus disease

When importing *aquatic animal products* of species referred to in Article 4.1.13.2. from a country, *zone* or *compartment* declared free from MoVD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 4.1.13.4. or 4.1.13.5. (as applicable), the place of production of the consignment is a country, *zone* or

compartment declared free from MoVD.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.2.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.13.3.

Article 4.1.13.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from Mourilyan virus disease

When importing *aquatic animal products* of species referred to in Article 4.1.13.2. from a country, *zone* or *compartment* not declared free from MoVD, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 4.1.13.3.

CHAPTER X.X.X.

KOI HERPESVIRUS DISEASE

Community comment

The Community agrees with the proposed chapter but would like to have its comment taken into account.

1. Case definition

Koi herpesvirus disease (KHVD) is a herpesvirus infection (16) capable of inducing a contagious and acute viraemia in common carp (*Cyprinus carpio*) and varieties such as koi carp and ghost carp (14).

2. Information for the design of surveillance programmes

a) Agent factors

Community comment

The Community would raise a concern regarding the inactivation procedures described in the last paragraph of point a). According to our scientific knowledge that paragraph should read:

The virus is inactivated by UV radiation and temperatures above 50°C for 1 minute. The following disinfectants are also effective for inactivation: iodophore at 200 mg l^{-1} for 20 minutes, benzalkonium chloride at 60 mg l^{-1} for 20 minutes, ethyl alcohol at 30% for 20 minutes, and sodium hypochlorite at 0,3 mg l^{-1} for 30 seconds, all at 15°C (20).

We would suggest the OIE to compare the proposed inactivation procedures with those described in reference 20:

20. KASAI H., MUTO Y. & YOSHIMIZU M. (2005). Virucidal effects of ultraviolet, heat treatment and disinfectants against koi herpesvirus (KHV). *Fish Pathology*, 40, 137-138.

The aetiological agent is koi herpesvirus (KHV) in the family Herpesviridae (16,39) although it has also been given the name carp nephritis and gill necrosis virus (CNGV) (27,18). Waltzek et al., 200538) provided evidence to support the classification of the virus as a herpesvirus, and named it cyprinid herpesvirus 3 (CyHV-3) following the nomenclature of other cyprinid herpesviruses: CyHV-1 (carp pox virus, fish papilloma) and CyHV-2 (goldfish haematopoietic necrosis virus). Estimates of the genome size of KHV vary from at least 150 kbp (11) to 277 kbp (18) to 295 kbp (38). Four genes, coding for a helicase, intercapsomeric triplex protein, DNA polymerase and major capsid protein have been identified and sequence analysis of these genes has shown that KHV is closely related to CyHV-1 and CyHV-2, and distantly related to channel catfish virus (CCV) herpesvirus (IcHV-1) (38). Estimates of virion size also vary. Nucleocapsids of negative stained virus have been measured at 103-112 nm diameter surrounded by an envelope (16,36,18). The nucleocapsids of thin sectioned virus have been measured at 80-110 and 110-120 nm diameter (4,16,25).

Serum from koi carp containing antibodies to KHV have been shown to cross-react with CyHV-1, a further indication that these viruses are closely related. Evidence of cross reacting antibodies was demonstrated in reciprocal ELISA and western blot analyses of serum from koi infected with CyHV-1 or KHV (1).

Comparisons of the genomes of KHV isolates from different geographic areas by restriction enzyme analysis (9,14) or nucleotide sequence analysis (28,13,19) have shown them to be practically identical. Likewise, the polypeptides of KHV isolates from different geographic areas were similar, although one isolate from Israel had two additional polypeptides (7,9).

The virus is inactivated by UV radiation and temperatures above 50°C for 1 minute. The following disinfectants are also effective for inactivation: iodophore at 200 mg l^{-1} for 30 seconds, benzalkonium chloride at 60 mg l^{-1} for 30 seconds, ethyl alcohol at 30% for 30 seconds and sodium hypochlorite at 200 mg l^{-1} for 30 seconds, all at 15°C (20).

b) Host factors

Community comment

The Community wouls suggest to make a reference to "Haenen, O.& Hedrich, R.P. (2006). Koi herpesvirus workshop. In: Section 2:Workshops. Bulletin of the European Association of Fish Pathologist. 26 (1), 26-37" in the third paragraph of point b). It should read:

Common carp (*Cyprinus carpio*) strains are currently the only reported host of KHVD and therefore considered to be most susceptible to KHV infection. Goldfish x common carp hybrids, produced by hybridizing male goldfish with female carp, have been reported to show some susceptibility to KHV infection. Approximately 50% of these hybrids examined at 25 days after intraperitoneal injection with a high dose of KHV possessed viral genomic DNA, as detected by PCR (17). In contrast to findings elsewhere, recent experimental data from Germany suggests a susceptibility of goldfish and grass carp to KHV but further confirmation of these findings are needed (17 and **Haenen, O.& Hedrich, R.P. (2006). Koi herpesvirus workshop. In: Section 2:Workshops. Bulletin of the European Association of Fish Pathologist. 26 (1), 26-37**" in the third paragraph of point b)). When sampling during surveillance programmes for KHV, common carp or strains such as koi or ghost (koi × common) carp should be preferentially selected followed by any common carp hybrids present on the site such as goldfish x common carp. Cyprinid species are commonly mixed together in polyculture systems and the risk of transmission of virus between species, during disease outbreaks, is high. If the findings from Germany were confirmed then, for disease surveillance purposes, all cyprinid species would need to be considered as potential covert carriers of KHV.

Naturally occurring KHV infections have only been recorded from common carp (*Cyprinus carpio carpio*), koi carp (*Cyprinus carpio koi*) and ghost carp (*Cyprinus carpio goi*) and hybrids of these varieties. All age groups of fish appear to be susceptible to KHVD (4,28,35), but under experimental conditions, 2.5-6 g fish were more susceptible than 230 g fish (25). Differential resistance to KHVD has been shown among different common carp strains (31) and other studies have suggested an age-related resistance (25). Morbidity of affected populations can be 100%, and mortality 70-80% (37,4), but the latter can be as high as 90 or 100% (4,36).

Carp are often raised in polyculture with other fish species, but no signs of disease or mortalities have been observed in those other fish, during KHVD outbreaks, under normal polyculture conditions. Refractory species include goldfish (*Carrassius auratus*), grass carp (*Ctenopharyngodon idellus*), silver carp (*Hypophthalmichthys molitrix*), tench (*Tinca* tinca), sturgeon (*Acipenser* sp.) Nile tilapia (*Oreochromis niloticus*), silver perch (*Bidyanus bidyanus*) and channel catfish (*Ictalurus punctatus*) (4,16,25,34).

The disease is temperature dependent, occurring between 16-25°C (16,6,25,28,35,36). Under experimental conditions the disease has caused high mortality at 28°C (10) but not at 29 or 30°C (18,24), nor at 13°C (10). However, viral DNA was detected in the fish by the PCR at 13°C, and it is possible that infected fish surviving at low temperatures may be reservoirs of the virus (10). The disease course can be rapid. The disease manifested itself in 3 days following the addition of naïve fish to a pond containing diseased fish (37), but usually under those circumstances it takes 8-21 days for the disease to be observed in the naïve fish (4,16). It is not known whether under natural conditions survivors of KHVD are persistently infected with virus, and if so, whether they shed the virus or for how long the fish retain the virus. Some of these aspects have been investigated in experimentally infected fish where it was shown that virus could persist in common carp infected at a permissive temperature and subsequently maintained at a lower than permissive temperature (32).

Common carp (*Cyprinus carpio*) strains are currently the only reported host of KHVD and therefore considered to be most susceptible to KHV infection. Goldfish x common carp hybrids, produced by hybridizing male goldfish with female carp, have been reported to show some susceptibility to KHV infection. Approximately 50% of these hybrids examined at 25 days after intraperitoneal injection with a high dose of KHV possessed viral genomic DNA, as detected by PCR (17). In contrast to findings elsewhere, recent experimental data from Germany suggests a susceptibility of goldfish and grass carp to KHV but further confirmation of these findings are needed (17). When sampling during surveillance programmes for KHV, common carp or strains such as koi or ghost (koi × common) carp should be preferentially selected followed by any common carp hybrids present on the site such as goldfish x common carp. Cyprinid species are commonly mixed together in polyculture systems and the risk of transmission of virus between species, during disease outbreaks, is high. If the findings from Germany were confirmed then, for disease surveillance purposes, all cyprinid species would need to be considered as potential covert carriers of KHV.

The reservoirs of KHVD are clinically infected fish and covert virus carriers among cultured, feral or wild fish. Virulent virus is shed via faeces, urine, gill and skin mucus. However, gill, kidney, and spleen are the organs in which KHV is most abundant during the course of overt infection (10).

The mode of transmission of KHV is horizontal but 'egg-associated' transmission (usually called 'vertical' transmission) cannot currently be ruled out. Horizontal transmission may be direct (fish to fish) or vectorial, water being the major abiotic vector. However, animate vectors (e.g. parasitic invertebrates and piscivorous birds) and fomites may also be involved in transmission.

c) Disease pattern

Disease patterns are influenced by water temperature, age and condition of the fish, population density and stress factors. The immune status of the fish will also be an important factor with both non-specific (interferon) and specific immunity (serum antibodies, cellular immunity) having important roles in herpesvirus infections. Clinical disease dominates at water temperatures above 18°C when the host immune response is at its optimum. Infected carp produce antibodies against the virus, which have been detected by ELISA methods at high serum dilution. Antibody has been detected in the serum at 3 weeks after experimental infection and in survivors after 1 year following a natural infection (27,1,32). Secondary and concomitant bacterial and/or parasitic

infections are commonly seen in diseased carp and may affect the mortality rate and display of signs (14).

Following the first reports of KHVD in Israel and Germany (15,25,4) the geographical range of the disease has become extensive. The disease has been spread to many countries world-wide, predominantly through the trade in koi carp before the current knowledge of the disease and means to detect it were available. It is now known to occur in, or has been recorded in fish imported into at least 22 different countries. In Europe this includes Austria, Belgium, Denmark, France, Italy, Luxembourg, The Netherlands, Poland, Switzerland and the United Kingdom (14,6,3,29). In Asia, China (Hong Kong), (14), Indonesia (34) Japan (28), Malaysia (14,21,22), Singapore (in fish imported from Malaysia), Taiwan (36) and Thailand (in fish imported into Germany, 14). Elsewhere, South Africa (14) and the USA (15,11,35) have reported occurrence of KHVD. It is likely that the virus is present in many more countries, but has not yet been identified there or reported

d) Control and prevention

Methods to control KHVD should mainly rely on avoiding exposure to the virus coupled with good hygiene and biosecurity practices. This is feasible on small farms supplied by spring or borehole water and a secure system to prevent fish entering the farm via the discharge water. Biosecurity measures should also include ensuring that new introductions of fish are from disease free sources and a quarantine system where new fish are held with sentinel fish at permissive temperatures for KHVD. The fish are then quarantined for a minimum of 4 weeks to 2 months before transfer to the main site and mixing with naïve fish. Hygiene measures on site should be similar to those recommended for SVC and include disinfection of eggs by iodophore treatment (20), regular disinfection of ponds, chemical disinfection of farm equipment, careful handling of fish to avoid stress and safe disposal of dead fish.

In rearing facilities with a controlled environment, elevation of water temperature above 26–28°C can reduce mortalities during KHVD outbreaks (7,27). Lowering the stocking density, and treating secondary infections may also help reduce the severity of the disease (34) A safe and effective vaccine is not currently widely available. However, attenuated virus has been used to vaccinate carp and protect the fish from virus challenge (27,24). The vaccine preparation induced antibody against the virus, but the duration of the protection is unknown. The vaccine is currently licenced for use in Israel and has been widely used in carp farms across the country

3. Diagnostic methods

Community comment

The Community would suggest to include a reference to the issue of the differentiation between infected and vaccinated animals. This new paragraph woul read:

Vaccinated fish may be tested positive by PCR, and until the exact sequence of the attenuated vaccine strain of KHV is known, no distinguishment of field and vaccine strain can be done at laboratories.

Diagnosis of KHVD in clinically affected fish can be achieved by virus isolation. However, the virus is isolated in only a limited number of cell lines and these cells can be difficult to handle. Also, cell culture isolation is not as sensitive as the published PCR-based methods to detect KHV DNA and is not considered to be a reliable diagnostic method for KHVD (14). Immunodiagnostic methods, similar to those used for diagnosis of SVC (e.g. , immunofluorescence (IF) tests or enzyme-linked immunosorbent assays (ELISAs)), may be suitable for rapid identification and diagnosis of KHVDbut have not been extensively reported, compared or validated. Until such time as validated tests are available then diagnosis of KHVD should not rely on just one test but a combination of 2 or 3 tests (14).

KHV infection produces a detectable antibody response in carp and enzyme immunoassays that reliably detect these antibodies have been published (27,1). Detection of antibodies may prove to be a valuable method of establishing previous exposure to KHV in apparently healthy fish. Until PCR-based methods have been developed that are able to detect latent virus in exposed fish then antibody assays may be the only surveillance tools available. However, due to insufficient knowledge of the

serological responses of fish to virus infections, the detection of fish antibodies to viruses has not thus far been accepted as a routine screening method for assessing the viral status of fish populations. However, the validation of some serological techniques for certain fish virus infections could arise in the near future, rendering the use of fish serology more widely acceptable for health screening purposes.

Fish material suitable for virological examination is:

- **Asymptomatic fish** (apparently healthy fish): Gill, kidney, spleen, and encephalon (any size fish).
- **Clinically affected fish:** Gill, kidney, spleen, gut and encephalon (any size fish).

a) Field diagnostic methods

During a KHVD outbreak there will be a noticeable increase in mortality in the population. All age groups of fish appear to be susceptible to KHVDalthough, generally, younger fish up to 1 year are more susceptible to clinical disease. Fish become lethargic, separate from the shoal and gather at the water inlet or sides of a pond and gasp at the surface of the water. Some fish may experience loss of equilibrium and disorientation but they may also show signs of hyperactivity. On closer examination of individual fish, typical clinical signs include pale discolouration or reddening of the skin, which may also have a rough texture, focal or total loss of epidermis, over- or under-production of mucus on the skin and gills. Other gross signs include enophthalmia (sunken eyes) and haemorrhages on the skin and base of the fins and fin erosion.

b) Clinical methods

There are no pathognomic gross lesions. Final diagnosis must await direct detection of viral DNA or antigen in tissues or virus isolation and identification. However, the most consistent gross pathology is seen in the gills and this can vary in extent from pale necrotic patches to extensive discolouration, severe necrosis and inflammation. Further examination can reveal erosion of primary lamellae, fusion of secondary lamellae, and swelling at the tips of the primary and secondary lamella. Other internal lesions are variable in occurrence and often absent in cases of sudden mortality. Other gross pathologies that have been reported include adhesions in the abdominal cavity with or without abnormal colouration of internal organs (lighter or darker). The kidney or liver may be enlarged, and they may also exhibit petechial or focal haemorrhages.

Presence of gross pathologies may also be complicated because diseased fish, particularly common carp, are also infested with ectoparasites such as *Argulus* sp., *Chilodonella* sp., *Cryptobia* sp., *Dactylogyrus* sp., *Gyrodactylus* sp., *Ichthyobodo* sp., *Ichtyophthirius* sp., *Trichodina* sp. and gill monogeneans, as well as numerous species of bacteria.

The histopathology of the disease can be non-specific and variable, but inflammation and necrosis of gill tissues is a consistent feature. Gills also exhibit hyperplasia and hypertrophy of branchial epithelium, and fusion of secondary lamellae and adhesion of gill filaments can be seen. Necrosis, ranging from small areas of necrotic epithelial cells of secondary lamellae to complete loss of the lamellae is observed. Branchial epithelial cells and leucocytes may have prominent nuclear swelling, margination of chromatin to give a "signet ring" appearance and pale diffuse eosinophilic intranuclear inclusions have been observed. Inflammation, necrosis and nuclear inclusions have been observed (individually or together) in other organs, particularly the kidney, but also in the spleen, pancreas, liver, brain, gut and oral epithelium.

c) Agent detection and identification methods

Detailed methods are not presented here because there have not been extensive comparison and validation of detection and identification methods for KHV. However, a short description of

available published methods is provided. Method recommendations will rely on further testing and validation and further data being obtained from laboratories that have developed the methods to decide if they are 'fit-for-purpose'.

- **Direct detection methods**

Community comment

Please, make reference to KHV.

i) Isolation of SVCV in cell culture

The virus can be isolated in a limited number of cell cultures, but cell culture isolation is not as sensitive as the PCR and is not considered to be a reliable diagnostic method for KHVD(14).

The virus replicates in koi fin cells (KF-1) (16), carp fin (CaF-2) and carp brain (CCB) cells (23), and in primary cells from fins of common or koi carp (25,27,18). Other cell lines used routinely for isolation of fish pathogenic viruses such as EPC, FHM, BF-2, CHSE-214 and RTG-2 cells are refractory to the virus (4,23,36,18). The virus is most abundant in gill, kidney, and spleen tissues during the course of overt infection (10) and it is recommended to sample these tissues for virus isolation. The optimum incubation temperature for virus isolation in KF-1 or CCB cells is 20°C but 8 to 12 days incubation may be required before a cytopathic effect (cpe) is observed (7).

ii) Identification of virus isolated in cell culture

Viruses isolated in cell culture must be definitively identified, as a number of different viruses have been isolated from carp exhibiting clinical signs resembling those of KHVD (14,5).

Rapid presumptive methods

Immunodiagnostic methods, similar to those used for presumptive identification of SVC (e.g. , immunofluorescence (IF) tests or enzyme-linked immunosorbent assays (ELISAs)), may well be suitable for rapid identification and diagnosis of KHVD(26,31).

Confirmatory identification methods

The most reliable method for confirmatory identification is by PCR, or one of its variants, which have also been used to identify KHV DNA directly in fish tissues (8,9,10,11,13,26,2,18,19,39).

A PCR based on the thymidine kinase (TK) gene of KHV was reported to be more sensitive than PCR methods described by Gilad et al., 20029) and Gray et al., 200211), and could detect 10 fg of KHV DNA (2); the PCR of Ishioka et al., 200519), based on the DNA polymerase gene, detected 100 fg of KHV DNA. The loop-mediated isothermal amplification (LAMP) method (13) was also based on the KHV TK gene, and was as sensitive as a PCR method developed by the same authors, but was more rapid than the PCR. The PCR described by Gray et al., 200211) was improved by Yuasa et al., 200539), and has been incorporated in the official Japanese guidelines for the detection of KHV

iii) Diagnostic methods for clinically diseased fish

Direct detection in fish tissues

KHV has been identified in touch imprints of liver, kidney and brain of infected fish by IF. Highest levels of positive immunofluorescence was seen in the kidney and the virus could be detected by IF on a kidney imprint 1 day post infection (26,31). Virus antigen has also been detected in infected tissues by an immunoperoxidase staining method. The virus antigen was detected by 2 days post infection in the kidney, and was also observed in the gills and liver (26). However, the detection of KHV by

immunostaining must be interpreted with care, as positive staining cells could result from cross-reaction with serologically related virus (e.g. CyHV-1) or a non-viral protein (26).

ELISA-based methods for direct detection of KHV antigen in infected tissues are under development in a number of laboratories worldwide but no methods have been published.

4. Rating of tests against purpose of use

The methods currently available for surveillance, detection and diagnosis of KHVDare listed in Table 1. The designations used in the table indicate: A = the method is currently the recommended method for reasons of availability, utility and diagnostic sensitivity and specificity; B = the method is a standard method with good diagnostic sensitivity and specificity; C = the method has application in some situations, but cost, accuracy or other factors severely limits its application; D = the method is currently not recommended for this purpose. Although not all of the tests listed as category A or B have undergone formal standardisation and validation (at least stages 1 and 2 of figure 1 of Chapter 1.1.2), their routine nature and the fact that they have been used widely without dubious results makes them acceptable.

Table 1. *KHVD surveillance, detection and diagnostic methods*

Method	Surveillance to declare freedom from infection	Presumptive diagnosis of infection or disease	Confirmatory diagnosis of infection or disease
Gross signs	D	B	D
Histopathology of tissues and organs	D	B	C
Isolation of in cell culture	D	C	D
Antibody-based assays to detect KHV antigen (IFAT, ELISA)	D	B	C
Transmission EM of tissues	D	B	C
PCR of tissue extracts	C	A	A
PCR – sequence analysis	NA	C	A
Detection of KHV antibodies in exposed fish (ELISA)	C	C	D

IFAT = Indirect fluorescent antibody test; ELISA = enzyme-linked immunosorbent assay;
EM = electron microscopy; PCR = polymerase chain reaction.

NOTE: Many diagnostic laboratories may encounter difficulties in obtaining antibodies against KHV that are suitable for use in immunodiagnostic tests. However, a limited number of monoclonal and polyclonal antibodies may be very soon available from commercial sources. It is quite likely that diagnostic kits will also soon be available from the same sources.

5. Corroborative diagnostic criteria

a) Definition of suspect case

A suspect case of KHVD is defined as the presence of typical clinical signs of the disease in a population of susceptible fish OR presentation of typical histopathology in tissue sections OR typical CPE in cell cultures without identification of the causative agent OR a single positive

result from one of the diagnostic assays described above.

b) Definition of confirmed case

A confirmed case is defined as a suspect case with subsequent identification of the causative agent by one of the serological or molecular assays described above OR a second positive result from a separate and different diagnostic assay described above.

6. Diagnostic/detection methods to declare freedom

There are no currently recommended methods for surveillance of susceptible fish populations for declaration of freedom from KHV. However, many laboratories are investigating further development of molecular-based methods to increase sensitivity (e.g. Real-time and nested PCR) or to reliably detect latent virus DNA. These assays may well prove suitable for surveillance programs.

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Community Comment

The Community would suggest the OIE to add the following reference:

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